Bayer Petition 09-328-01 for Determination of Non-regulated Status of Double Herbicide-tolerant Soybean (*Glycine Max*) Event FG72

OECD Unique Identifier:
FG72

Final Environmental Assessment

August 2013

Agency Contact
Cindy Eck
Biotechnology Regulatory Services
4700 River Road
USDA, APHIS
Riverdale, MD 20737
Fax: (301) 734-8669

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA'S TARGET Center at (202) 720–2600 (voice and TDD).

To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326–W, Whitten Building, 1400 Independence Avenue, SW, Washington, DC 20250–9410 or call (202) 720–5964 (voice and TDD). USDA is an equal opportunity provider and employer.

Mention of companies or commercial products in this report does not imply recommendation or endorsement by the U.S. Department of Agriculture over others not mentioned. USDA neither guarantees nor warrants the standard of any product mentioned. Product names are mentioned solely to report factually on available data and to provide specific information.

This publication reports research involving pesticides. All uses of pesticides must be registered by appropriate State and/or Federal agencies before they can be recommended.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS AND ABBREVIATIONS

4-HPPD	4-hydroxyphenylpyruvate dioxygenase
AIA	advanced informed agreement
AMS	Agricultural Marketing Service
AOSCA	American Organization of Seed Certifying Agencies
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services (within USDA–APHIS)
Bt	*Bacillus thuringiensis* protein
CAA	Clean Air Act
CBD	Convention on Biological Diversity
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations (United States)
CH_4	methane
CO_2	carbon dioxide
CWA	Clean Water Act
DNA	deoxyribonucleic acid
DKN	diketonitrile
EA	environmental assessment
EFED	Environmental Fate and Effects Division
EIQ	Environmental Impact Quotient
EIS	environmental impact statement
EO	Executive Order
EPA	U.S. Environmental Protection Agency
EPSPS	5-enolpyruvylshikimate-3-phosphate synthase
ESA	Endangered Species Act of 1973
ESPP	Endangered Species Protection Program
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FSANZ	Food Standards Australia New Zealand
FR	Federal Register
FQPA	Food Quality Protection Act
GE	genetically engineered

GHG	greenhouse gas
HED	Health Effects Division
IFT	isoxaflutole
IP	Identity Preservation
IPCC	Intergovernmental Panel on Climate Change
ISPM	International Standard for Phytosanitary Measure
IPPC	International Plant Protection Convention
LD50	lethal dose that kills 50% of the animals being tested
LMO	Living modified organism
MOA	Mode of Action
N_2O	nitrous oxide
NABI	North American Biotechnology Initiative
NAPPO	North American Plant Protection Organization
NEPA	National Environmental Policy Act of 1969 and subsequent amendments
NHPA	National Historic Preservation Act
NMFS	National Marine Fisheries Service
NOEL	no observable effect level
NOP	National Organic Program
NPS	non-point source
NRC	National Research Council
OECD	Organization for Economic Cooperation and Development
PIP	Plant incorporated protectants
PPRA	Plant Pest Risk Assessment
PPA	Plant Protection Act of 2000
PRA	Pest Risk Assessment
RSPM	Regional Standards for Phytosanitary Measures
RUP	Restricted Use Pesticide
TES	threatened and endangered species
TSCA	Toxic Substances Control Act
U.S.	United States
USFWS	United States Fish and Wildlife Services
USDA	U.S. Department of Agriculture
USDA-ERS	U.S. Department of Agriculture-Economic Research Service

USDA-FAS	U.S. Department of Agriculture-Foreign Agricultural Service
USDA-NASS	U.S. Department of Agriculture-National Agricultural Statistics Service
USDA-NOP	U.S. Department of Agriculture-National Organic Program
USC	United States Code
WPS	Worker Protection Standard for Agricultural Pesticides

1 PURPOSE AND NEED

1.1 Coordinated Framework Review and Regulatory Review

"Protecting American agriculture" is the basic charge of the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). APHIS provides leadership in ensuring the health and care of plants and animals. The agency improves agricultural productivity and competitiveness, and contributes to the national economy and the public health. USDA asserts that all methods of agricultural production (conventional, conventional with genetically engineered crops, and organic systems) can provide benefits to the environment, consumers, and farm income.

Since 1986, the United States government has regulated genetically engineered (GE) organisms pursuant to a regulatory framework known as the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) (51 FR 23302; 57 FR 22984). The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products and explains how federal agencies will use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework is based on several important guiding principles: (1) agencies should define those transgenic organisms subject to review to the extent permitted by their respective statutory authorities; (2) agencies are required to focus on the characteristics and risks of the biotechnology product, not the process by which it is created; (3) agencies are mandated to exercise oversight of GE organisms only when there is evidence of “unreasonable” risk.

The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in regulating GE organisms: USDA APHIS, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

USDA-APHIS

APHIS regulations at 7 Code of Federal Regulations (CFR) part 340, which were promulgated pursuant to authority granted by the Plant Protection Act of 2000, as amended (7 United States Code (U.S.C.) 7701–7772), regulate the introduction (importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is no longer subject to the plant pest provisions of the Plant Protection Act or to the regulatory requirements of 7 CFR part 340 when APHIS determines that it is unlikely to pose a plant pest risk. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation (7 CFR 340.2) and is also considered a plant pest. A GE organism is also regulated under Part 340 when APHIS has reason to believe that the GE organism may be a plant pest or APHIS does not have information to determine if the GE organism is unlikely to pose a plant pest risk.

A person may petition the agency that a particular regulated article is unlikely to pose a plant pest risk, and, therefore, is no longer regulated under the plant pest provisions of the Plant

Protection Act of 2000 or the regulations at 7 CFR 340. The petitioner is required to provide information under § 340.6(c)(4) related to plant pest risk that the agency may use to determine whether the regulated article is unlikely to present a greater plant pest risk than the unmodified organism. A GE organism is no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act when APHIS determines that it is unlikely to pose a plant pest risk.

Under the authority of the plant pest provisions of the Plant Protection Act of 2000 and 7 CFR part 340, APHIS has issued regulations for the safe development and use of GE organisms. As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of GE organisms. When a petition for nonregulated status is submitted, APHIS must make a determination if the GE organism is unlikely to pose a plant pest risk. If APHIS determines based on its Plant Pest Risk Assessment (PPRA) that the GE organism is unlikely to pose a plant pest risk, the genetically engineered organism is no longer subject the plant pest provisions of the Plant Protection Act and 7 CFR part 340.

Environmental Protection Agency

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), EPA regulates the use of pesticides, including plant-incorporated protectants, requiring registration of a pesticide for a specific use prior to distribution or sale of the pesticide for a proposed use pattern. EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and storage and disposal practices. Prior to registration for a new use for a new or previously registered pesticide, EPA must determine through testing that the pesticide will not cause unreasonable adverse effects on humans, the environment, and non-target species when used in accordance with label instructions. EPA must also approve the language used on the pesticide label in accordance with 40 CFR part 158. Once registered, a pesticide may not legally be used unless the use is consistent with the approved directions for use on the pesticide's label or labeling. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment.

EPA also sets tolerances for residues of pesticides on and in food and animal feed, or establishes an exemption from the requirement for a tolerance, under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is required, before establishing pesticide tolerance, to reach a safety determination based on a finding of reasonable certainty of no harm under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). FDA enforces the pesticide tolerances set by EPA.

Food and Drug Administration

FDA regulates GE organisms under the authority of the FFDCA (21 U.S.C. 301 *et seq.*). The FDA published its policy statement concerning regulation of products derived from new plant varieties, including those derived from genetic engineering, in the *Federal Register* on May 29, 1992 (57 FR 22984). Under this policy, FDA implements a voluntary consultation process to ensure that human food and animal feed safety issues or other regulatory issues, such as labeling, are resolved before commercial distribution of bioengineered food. This voluntary consultation process provides a way for developers to receive assistance from FDA in complying with their obligations under Federal food safety laws prior to marketing.

More recently, in June 2006, FDA published recommendations in “Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” (FDA, 2012b)for establishing voluntary food safety evaluations for new non-pesticidal proteins produced by new plant varieties intended to be used as food, including bioengineered plants. Early food safety evaluations help make sure that potential food safety issues related to a new protein in a new plant variety are addressed early in development. These evaluations are not intended as a replacement for a biotechnology consultation with FDA, but the information may be used later in the biotechnology consultation.

1.2 Petition for Determination of Nonregulated Status: Double Herbicide-resistant Soybean Event FG72

Bayer CropScience of Research Triangle Park, NC (Bayer) submitted petition 09-328-01 to APHIS in June 2011 seeking a determination of nonregulated status for soybean event FG72 that is resistant to the herbicides glyphosate and isoxaflutole. FG72 soybean is currently regulated under 7 CFR part 340. Interstate movements and field trials of FG72 soybean have been conducted under permits issued or notifications acknowledged by APHIS since 2001. These field trials were conducted in diverse growing regions within the U.S., including Indiana, Iowa, Nebraska, Florida, Arizona, Illinois, Michigan, Missouri, and Minnesota. Data resulting from these field trials are described in the FG72 petition (Bayer, 2011c) and analyzed for plant pest risk in the APHIS Plant Pest Risk Assessment (PPRA) (USDA-APHIS, 2012d).

The petition stated that APHIS should not regulate FG72 soybean because it does not present a plant pest risk. In the event of a determination of nonregulated status, the nonregulated status would include FG72 soybean, any progeny derived from crosses between FG72 and conventional soybean, including crosses of FG72 with other biotechnology-derived soybean that are no longer subject to subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act of 2000.

1.3 Purpose of Product

Weed competition in a soybean field may dramatically reduce soybean yield. Consequently, weed management is a major concern in soybean production. FG72 soybean was developed to enable the use of isoxaflutole to manage soybean weed populations, including those weed populations that are resistant to glyphosate, without injury to soybean plants.

Under typical field conditions, application of glyphosate or isoxaflutole would disrupt soybean aromatic amino acid and carotenoid biosynthesis, respectively (USDA-APHIS, 2012d). FG72 soybean is engineered to be resistant to glyphosate and isoxaflutole. This double herbicide-resistant phenotype is enabled by stable introduction of the *2mEPSPS* and *HPPD W336* genes[1]. *2mEPSPS* is derived from *Zea mays* and confers resistance to glyphosate through activity of the

---

[1] Generally, standard genetic nomenclature dictates that gene names are italicized, while the respective protein names are not italicized.

2mEPSPS protein. *HPPD W336* is derived from the A32 strain of *Pseudomonas fluorescens* and confers resistance to isoxaflutole through activity of the HPPD W336 protein. Both proteins impart herbicide resistance to FG72 soybean in a mechanistically similar manner, where 2mEPSPS and HPPD W336 are less susceptible to competitive inhibition by glyphosate and isoxaflutole, respectively, than native[2] soybean EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) or 4-HPPD (4-hydroxyphenylpyruvate dioxygenase) proteins.

1.4 Purpose and Need for APHIS Action

As required by 7 CFR 340.6, APHIS must respond to petitioners that request a determination of the regulated status of genetically engineered organisms, including GE plants such as FG72 soybean. APHIS has prepared this Environmental Assessment (EA) to consider the potential environmental effects of an agency determination of nonregulated status consistent with Council of Environmental Quality's (CEQ) NEPA regulations and the USDA and APHIS NEPA implementing regulations and procedures(40 CFR parts 1500-1508, 7 CFR part 1b, and 7 CFR part 372). This EA has been prepared in order to specifically evaluate the effects on the quality of the human environment[3] that may result from a determination of nonregulated status of FG72 soybean.

1.5 Public Involvement

APHIS routinely seeks public comment on EAs prepared in response to petitions seeking a determination of nonregulated status of a regulated GE organism. APHIS does this through a notice published in the *Federal Register*. The issues discussed in this EA were developed by considering the public concerns as well as issues raised in public comments submitted for other EAs of GE organisms, concerns raised in lawsuits, as well as those issues of concern that have been raised by various stakeholders. These issues, including those regarding the agricultural production of soybean using various production methods and the environmental and food/feed safety of GE plants were addressed to analyze the potential environmental impacts of FG72 soybean.

The draft EA, the petition submitted by Bayer, and APHIS's PPRA were published for public comment on July 13, 2012 (77 FR 41358). Comments received by the end of the 60-day period were carefully analyzed to identify potential environmental and interrelated economic issues and impacts that APHIS may determine should be considered in the evaluation of the petition. A total of 5,096 comments were received during the comment period[4]. The issues that were raised in the public comments which were related to the Bayer FG72 soybean petition included:

- Development of herbicide resistant weeds and weeds with multiple resistance
- Use of herbicides on herbicide resistant crops including increased herbicide use and change in use patterns
- The effects of FG72 soybean and its associated herbicide use on conservation tillage

[2] Native refers to genes and proteins that are already present in soybean.
[3] Under NEPA regulations, the "human environment" includes "the natural and physical environment and the relationship of people with that environment" (40 CFR §1508.14).
[4] Comment documents may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0029

• The potential for increased weediness of FG72 soybean volunteers
• The fate of glyphosate and isoxaflutole in air, water, and soil
• The effects of glyphosate and isoxaflutole use on biological organisms including Threatened and Endangered Species
• The effects of FG72 soybean and its associated herbicide use on climate change
• The effect of glyphosate drift on outcrossing to weedy or wild relatives
• The effect of glyphosate and isoxaflutole drift on nontarget plants including nontarget crops
• Increase in plant pathogens or susceptibility to plant pathogens from the use of herbicides
• The effects of FG72 soybean and associated glyphosate and isoxaflutole use on human health
• Concern that cross-pollination between GE and organic or crops for GE-sensitive markets will affect sales for growers of these crops.
• The economic costs of herbicide resistant weeds
• Concerns that Bayer FG72 soybean is not approved in all export markets.

APHIS evaluated these raised issues and the submitted documentation. APHIS used these comments to inform APHIS' determination decision of the regulated status of FG72 soybean and to assist APHIS in determining whether an Environmental Impact Statement (EIS) was required prior to the determination decision of the regulated status of this soybean variety.

1.6 Issues Considered

The list of resource areas considered in this draft EA were developed by APHIS through experience in considering public concerns and issues raised in public comments submitted for this petition and other EAs of GE organisms. The resource areas considered also address concerns raised in previous and unrelated lawsuits, as well as issues that have been raised by various stakeholders in the past. The resource areas considered in this EA can be categorized as follows:

Agricultural Production Considerations:

- Acreage and range of soybean production
- Agronomic practices

Environmental Considerations:

- Soil Quality
- Water resources
- Air quality
- Climate change
- Animal communities
- Plant communities
- Gene flow and weediness
- Microorganisms
- Biodiversity

Public Health Considerations:

- Human health and worker safety

Livestock Health Considerations:

- Animal feed/livestock health

Socioeconomic Considerations:

- Domestic economic environment
- Organic soybean production
- Trade economic environment

2 AFFECTED ENVIRONMENT

2.1 Agricultural Production of Soybean

2.1.1 Range and Acreage of Soybean Production

Soybean production in the United States extends over a wide range of geographies and regions, generally extending south of North Dakota to Texas and east of Nebraska to New Jersey. Within this wide geography, the major soybean production areas of the United States may be generally characterized as the Midwest, Southeast, and Eastern Coastal regions (Figure 1). Soybean production is divided into 3 major regions in this EA based on geographical differences in the weed spectrum with a particular interest on glyphosate resistant weed populations. These soybean production regions were based principally on the regional chapters of the Weed Science Society of America (WSSA). In 2012, approximately 77.2 million acres of soybeans (USDA-NASS, 2012b) were commercially cultivated in 31 states (Table 1). The five leading soybean production states in 2012 were:

- Iowa (9,350,000 planted acres);
- Illinois (9,050,000 planted acres);
- Minnesota (7,050,000 planted acres);
- Missouri (5,400,000 planted acres); and
- Indiana (5,150,000 planted acres);

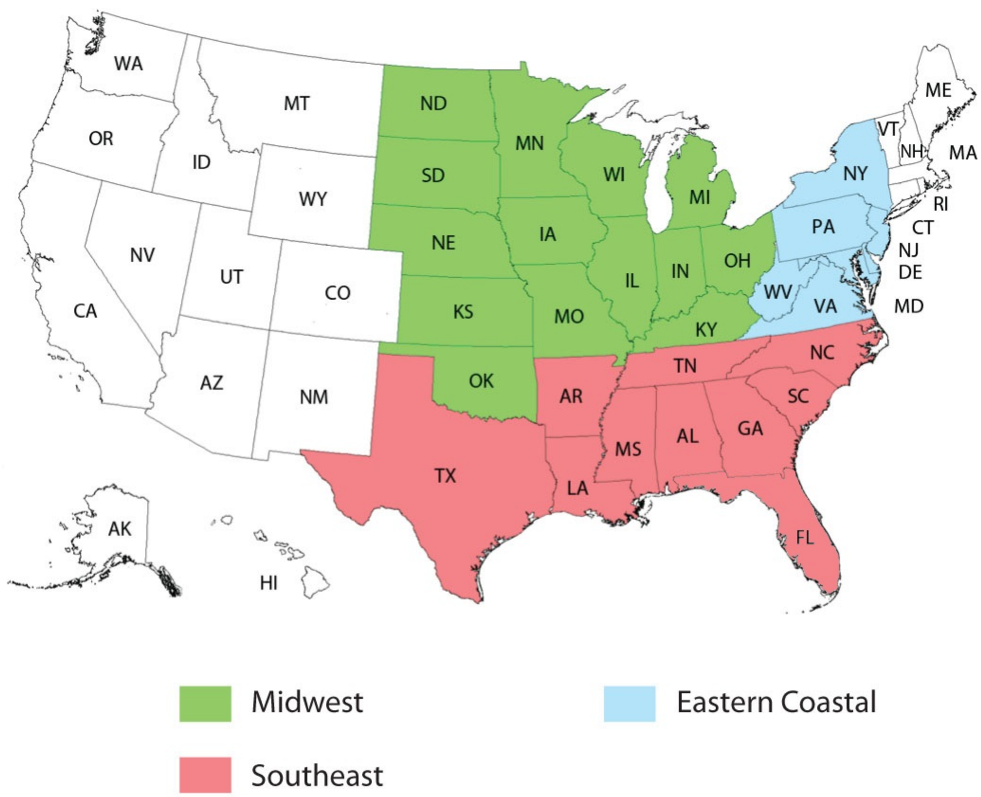


Figure 1. United States soybean production regions

Table 1. Planted soybean acreage in U.S. States, 2012

State	Planted Soybean Acreage	State	Planted Soybean Acreage	State	Planted Soybean Acreage
Alabama	340,000	Louisiana	1,130,000	North Dakota	4,750,000
Arkansas	3,200,000	Maryland	480,000	Ohio	4,600,000
Delaware	170,000	Michigan	2,000,000	Oklahoma	420,000
Florida	21,000	Minnesota	7,050,000	Pennsylvania	530,000
Georgia	220,000	Mississippi	1,970,000	South Carolina	380,000
Illinois	9,050,000	Missouri	5,400,000	South Dakota	4,750,000
Indiana	5,150,000	Nebraska	5,050,000	Tennessee	1,260,000
Iowa	9,350,000	New Jersey	96,000	Texas	125,000
Kansas	4,000,000	New York	315,000	Virginia	590,000
Kentucky	1,480,000	North Carolina	1,590,000	West Virginia	21,000
				Wisconsin	1,710,000

Source: USDA-NASS (2012c)

2.1.2 Agronomic Practices

In this EA, conventional farming is defined as any farming system where synthetic inputs maybe used. This includes synthetic fertilizers and pesticides. Conventional farming covers a broad scope of farming practices, ranging from farmers who occasionally use fertilizers and pesticides to those farmers whose harvest depends on regular inputs of synthetic fertilizers and pesticides. Conventional farming also includes the use of GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act of 2000 (USDA-APHIS, 2012c).

Soybean varieties are developed and adapted to certain geographical zones[5] (Helsel and Minor, 1993; NSRL, 2011). GE herbicide-resistant soybean varieties represents the most common soybean variety cultivated in the United States, accounting for 93 percent of soybean varieties planted in 2012 (USDA-ERS, 2012a). Among the GE herbicide- resistant soybean varieties currently available, glyphosate- resistant varieties represent the vast majority that is planted in the United States (NRC, 2010a). While soybean agronomic practices are dependent on geography and variety, some practices are shared across production regions. These include agronomic practices related to crop rotation, fertilization, and pest management. Irrigation is not discussed in this subsection, but rather in Subsection 2.2.2 – Water Resources.

Tillage

The broad adoption of glyphosate-resistant soybean varieties and glyphosate has influenced several aspects of soybean management. In particular, tillage trends have been affected. Prior to planting, the soil must be stripped of weeds that would otherwise compete with soybean for

---

[5] Also known as soybean maturity groups. See: http://www.nsrl.illinois.edu/general/soyprod.html (Last accessed January, 2013).

space, water, and light. Tillage represents a mechanical means of weed control and is generally characterized by the amount of remaining in-field residue and may be classified as conservation ($\geq$ 30 percent), reduced (15-30 percent), or intensive (0-15 percent) (CTIC, 2008). Conservation tillage practices by U.S. soybean growers increased following the commercialization of glyphosate-resistant soybean in 1996 The adoption of conservation tillage practices by U.S. soybean growers increased from 51 percent of planted acres in 1996 to 63 percent in 2008, or an addition of 12 million acres.(CTIC, 2008; NRC, 2010a). Conservation tillage adoption is generally associated with broad-spectrum herbicide use, due to the capacity of broad-spectrum herbicides to burn down a variety of weed populations prior to planting a crop. Though the causality between herbicide-resistant soybean adoption and conservation tillage may be debated (Fernandez-Cornejo et al., 2003; Mensah, 2007), most empirical evidence suggests a direct relationship between grower adoption of herbicide-resistant crops and conservation tillage (NRC, 2010a).

Crop Rotation

At the conclusion of a growing season, soybean farmers have the option to plant soybean or alternative crops the following season. The planting of soybean on the same field in successive years is known as continuous soybean production. In contrast, the planting of an alternative crop after soybean is known as crop rotation.

The purpose of growing soybean in rotation is to improve yield and profitability of one or both crops; decrease the need for additional nitrogen on the crop following soybean; increased residue cover; mitigate or disruption of disease, insect, and weed cycles; reduce soil erosion; increase soil organic matter; improve soil tilth and soil physical properties; and reduced runoff of nutrients, herbicides, and insecticides (Al-Kaisi et al., 2003).

Crop rotation is a common practice on U.S. soybean fields, with approximately 95 percent of the soybean acreage planted in some form of a crop rotation system since 1991 (USDA-ERS, 2011b). A variety of crops may be rotated with soybean. In terms of acreage however, corn is the most commonly rotated crop. In a survey of major corn/soybean production states, corn and soybean were alternated on 72 to 80 percent of acreage, other rotations were grown on 16 to 20 percent of acreage, and soybean was grown continuously on 5 to 12 percent of acreage between 1996-2002 (Sandretto and Payne, 2006). Other crops that may be rotated with soybean include wheat, cotton, rice, sorghum, barley, oats, and dry beans (Table 2).

The mitigation of pest cycles on an agricultural field is one of the primary benefits of crop rotation. The rotation of other crops following soybean production may disrupt pest life cycles that are more adapted to soybean field cultivation than other crops (Poole, 2004) through the creation of a relatively unstable agroecosystem (Weller et al., 2010). For example, crop rotation may encourage the use of alternative herbicides to further control broadleaf weeds in the same field in successive years that would not otherwise be used if continuous soybean was grown (Gunsolus, 2012).

Table 2. Rotation practices in the United States following soybean production, 2008

Total Soybean Acreage in the United States	Major Crops Following Soybean in Rotation	Total Acreage of Rotation Crop in United States	Rotation Crop Acres Following Soybean
75,718			
	Corn	80,130	51,500
	Soybean	75,037	10,866
	Sorghum	4,020	841
	Cotton	3,767	1,570
	Wheat	37,414	8,396
	Barley	2,159	41
	Oats	1,995	98
	Rice	2,301	1,042
	Alfalfa	1,864	162
	Sugar Beets	830	144
	Potatoes	334	32
	Dry Beans	1,183	35
	Dry Peas	520	38
	Millet	250	41
	Flax	345	76
	Other (various vegetables)	452	155

This U.S. summary was developed by compiling the data from all three regional summaries. All acreage is expressed as 1000s of acres.
Source: Modified from Table VIII-24 in Monsanto (2012)

Fertilization

In order to ensure optimal yield, fertilizer may be added to a soybean field to replenish nutrients in the soil. In particular, nitrogen is important for yield. Soybeans may remove up to 70 pounds of nitrogen from the soil when a 50-bushel yield of soybean is attained (Hoeft et al., 2000). USDA-ERS estimates that less than 40 percent of soybean acres in the United States receive nitrogen fertilizer (USDA-ERS, 2010c). In 2012, the most recent year of chemical survey data from USDA-NASS[6], the following fertilizers were applied on U.S. soybean acres (USDA-NASS, 2013a):

- Nitrogen – 321,100,000 lbs.
- Phosphate – 1,329,300,000 lbs.
- Potash – 2,214,700,000 lbs.

Pest Management

[6] USDA-NASS chemical survey data are determined through the use of USDA-NASS reports from 19 program states. This chemical use date includes agronomic inputs, such as fertilizer and pesticides. Program states include AR; IL; IN; IA; KS; KY; LA; MI; MN; MS; MO; NE; NC; ND; OH; SD; TN; VA; and WI.

Pest management is an integral part of soybean production. Chemical inputs, in particular pesticides, may be used to control various fungal, insect, and weed pests in soybean fields. In 2012, herbicides were applied to the 98 percent of soybean acres, followed by insecticides (18 percent) and then fungicides (11 percent)(USDA-NASS, 2013a).

Fungicide use in soybean is much lower than insecticide or herbicide use. In 2012, approximately 11 percent of U.S. soybean acres were treated with fungicides, with no fungicide application exceeding 5 percent of U.S. soybean acreage (Table 3). In total, 984,000 lbs. of fungicides were applied to U.S. soybean acres in 2012 (USDA-NASS, 2013a; USDA-NASS, 2013b).

U.S. soybean growers generally face reduced pest pressure from insects, due in large part to the capacity of soybeans to experience limited insect herbivory without a reciprocal loss in grain yield (Penn State Extension, 2011). This recalcitrance to insect damage is evident in the relatively low use of insecticides on cultivated soybean acreage; in 2012, insecticides were applied on 18 percent of soybean acres, with no single insecticide exceeding 6 percent of chemically-treated acreage (Table 4). Also in 2012, insecticide application on U.S. soybean acreage totaled 3,773,000 lbs. (USDA-NASS, 2013a) (USDA-NASS, 2007a).

Table 3. Soybean fungicide use, 2012

Active ingredient	Area Applied (percent)	Applications	Rate per Application (lbs. per acre)	Rate per Crop Year (lbs. per acre)	Total Applied
Azoxystrobin	4	1.2	0.108	.128	372,000
Propiconazole	2	1	0.085	0.087	125,000
Pyraclostrobin	5	1	0.101	0.101	397,000
Tetraconazole	5	1	0.06	0.06	17,000
Trifloxystrobin	1	1	0.075	0.075	73,000

Source: (USDA-NASS, 2013b)

Table 4. Soybean insecticide use, 2012

Active ingredient	Area Applied (percent)	Applications	Rate per Application (lbs. per acre)	Rate per Crop Year (lbs. per acre)	Total Applied
Acephate	1	1.4	0.706	0.958	989,000
Beta-cyfluthrin	≤ 0.5	1	0.023	0.023	4,000
Bifenthrin	3	1.1	0.07	0.076	153,000
Chlorpyrifos	6	1.1	0.422	0.448	2,090,000
Cyfluthrin	1	1.1	0.054	0.059	44,000
Cypermethrin	≤ 0.5	1	0.108	0.113	10,000
Diflubenzuron	≤ 0.5	1.1	0.026	0.029	6,000

Active ingredient	Area Applied (percent)	Applications	Rate per Application (lbs. per acre)	Rate per Crop Year (lbs. per acre)	Total Applied
Dimethoate	1	1	0.464	0.464	276,000
Esfenvalerate	≤ 0.5	1	0.04	0.04	10,000
Flubendiamide	≤ 0.5	1	0.062	0.062	21,000
Gamma-cyhalothrin	1	1	0.007	0.008	6,000
Lamda-cyhalothrin	6	1.1	0.03	0.032	141,000
Thiamethoxam	1	1.2	0.035	0.042	19,000
Zeta-cypermethrin	1	1	0.005	0.005	4,000

Source: (USDA-NASS, 2013b)

Weed management is an integral component of any soybean production system. If weeds in a soybean field are left unmanaged, a 12 – 80 percent loss in yield may occur (Barrentine, 1989). The management of weeds in U.S. soybean production may involve the use of tillage, though the application of synthetic chemical herbicides is more common. Individual weed species, including glyphosate-resistant species, are discussed in Subsection 2.3.2 – Plant Communities.

Prior to the planting of soybean seeds, tillage may be used to strip the soil of weeds that would otherwise compete with soybeans for space, water, and light. Tillage represents a mechanical means of weed control and is generally characterized by the amount of remaining in-field residue and may be classified as conservation (≥ 30 percent), reduced (15-30 percent), or intensive (0-15 percent) (CTIC, 2008). In 2006, 31.6 percent of planted soybean acres were cultivated for weed control (23,000,000 out of 72,900,000 planted soybean acres) (USDA-ERS, 2013b). Also in 2006, 49.2 percent plant residue remained in a typical soybean field at planting following 1.2 tillage operations (USDA-ERS, 2013b).

Although tillage may control soybean weeds, fuel costs and machine maintenance may represent substantial farm expenditures (NRC, 2010a). This fact and the availability of herbicide technology have driven producers to increasingly adopt chemical management strategies. In 2006, 98 percent of soybean acreage was treated with synthetic herbicides (USDA-NASS, 2013a). Herbicides have different ways of acting on plant physiology (i.e., modes of action or MOA) to affect the health of a weed, and herbicides may also be applied pre-plant[7], pre-emergence[8], or post-emergence[9] in a soybean field. In 2012, the most commonly-applied herbicide in soybean was glyphosate, with 70,826,000 lbs. of glyphosate potassium salt applied on 59 percent of U.S. soybean acreage, followed by 29,550,000 lbs. of glyphosate isopropylamine salt applied on 30 percent of U.S. soybean acreage (USDA-NASS, 2013b). Despite the common use of glyphosate on U.S. soybean fields, 44 other herbicides were also used in soybean, though use of these alternative herbicides did not exceed 11 percent of planted soybean acreage or 4,098,000 lbs. of applied active ingredient Table 5.

[7] Before soybean seeds have been planted, also referred to as “burn-down” herbicide application.
[8] Before soybean seeds have germinated.
[9] After soybean seeds have germinated.

Table 5. Soybean herbicide use, 2012

Active ingredient	Area Applied (percent)	Applications	Rate per Application (lbs. per acre)	Rate per Crop Year (lbs. per acre)	Total Applied
2,4-D	≤ 0.5	1	0.132	0.135	25,000
2,4-D; 2-EHE	11	1	0.51	0.519	4,098,000
2,4-D; BEE	≤ 0.5	1	0.329	0.329	68,000
2,4-D; Dimethyl Salt	4	1	0.544	0.559	1,830,000
Acetochlor	1	1.1	0.907	0.99	635,000
Acifluorfen	1	1.1	0.275	0.303	210,000
Carfentrazone	≤ 0.5	1	0.01	0.01	1,000
Chlorimuron-Ethyl	11	1.1	0.022	0.023	187,000
Clethodim	9	1.1	0.073	0.082	524,000
Cloransulam-Methyl	4	1	0.024	0.025	83,000
Dicamba diglycolamine salt	≤ 0.5	1	0.113	0.113	18,000
Dicamba dimethyl salt	≤ 0.5	1	0.223	0.223	69,000
Dimethenamid-P	1	1	0.278	0.291	235,000
Fenoxaprop	≤ 0.5	1.2	0.031	0.036	7,000
Fluazifop-P-Butyl	3	1	0.094	0.097	195,000
Flumetsulam	≤ 0.5	1	0.082	0.082	14,000
Flumiclorac-Pentyl	1	1.2	0.028	0.033	35,000
Flumioxazin	11	1	0.075	0.076	602,000
Fluthiacet	2	1.2	0.005	0.006	10,000
Fomesafen	8	1.1	0.208	0.235	1,347,000
Glyphosate	7	1.5	0.838	1.22	6,539,000
Glyphosate Ammonium	3	1.6	0.373	0.587	1,253,000
Glyphosate Dim. Salt	2	1.5	0.864	1.316	2,421,000
Glyphosate Iso. Salt	30	1.6	0.843	1.33	29,550,000
Glyphosate Pot. Salt	59	1.7	0.979	1.628	70,826,000
Imazamox	≤ 0.5	1	0.03	0.03	6,000
Imazaquin	≤ 0.5	1	0.083	0.083	23,000
Imazaquin mon. salt	≤ 0.5	1	0.031	0.031	11,000
Imazethapyr	5	1	0.052	0.052	205,000
Imazethapyr, Ammon.	≤ 0.5	1.1	0.046	0.048	16,000
Lactofen	2	1	0.144	0.144	192,000
Metolachlor	≤ 0.5	1	1.065	1.065	292,000
Metribuzin	3	1.1	0.246	0.268	675,000
Paraquat	3	1.2	0.376	0.436	813,000
Pendimethalin	2	1	0.874	0.888	1,559,000

Active ingredient	Area Applied (percent)	Applications	Rate per Application (lbs. per acre)	Rate per Crop Year (lbs. per acre)	Total Applied
Quizalofop-P-Ethyl	2	1.1	0.064	0.072	118,000
Rimsulfuron	≤ 0.5	1	0.019	0.019	4,000
S-Metolachlor	7	1.1	0.991	1.097	5,391,000
Saflufenacil	4	1	0.028	0.028	80,000
Sethoxydim	≤ 0.5	1	0.212	0.212	63,000
Sulfentrazone	8	1	0.17	0.172	1,078,000
Thifensulfuron	5	1	0.009	0.009	31,000
Tribenuron-Methyl	1	1	0.01	0.01	10,000
Trifluralin	2	1	0.79	0.815	1,306,000

Source: (USDA-NASS, 2013b)

2.2 Physical Environment

2.2.1 Soil Quality

Soil consists of solids (minerals and organic matter), liquid, and gases. This body of inorganic and organic matter is home to a wide variety of fungi, bacteria, and arthropods, as well as the growth medium for terrestrial plant life (USDA-NRCS, 2004). Soil is characterized by its layers that can be distinguished from the initial parent material due to additions, losses, transfers, and transformations of energy and matter (USDA-NRCS, 1999). It is further distinguished by its ability to support rooted plants in a natural environment. Soil plays a key role in determining the capacity of a site for biomass vigor and production in terms of physical support, air, water, temperature moderation, protection from toxins, and nutrient availability. Soils also determine a site's susceptibility to erosion by wind and water, and a site's flood attenuation capacity.

Soil properties change over time: temperature, its acidity or alkalinity (pH), soluble salts, amount of organic matter, the carbon-nitrogen ratio, and numbers of microorganisms and soil fauna all change seasonally as well as over extended periods of time (USDA-NRCS, 1999). Soil texture and organic matter levels directly influence soil shear strength, nutrient holding capacity, and permeability. Soil taxonomy was established to classify soils according to the relationship between soils and the factors responsible for their character (USDA-NRCS, 1999). Soils are organized into four levels of classification, the highest being the soil order. Soils are differentiated based on characteristics such as particle size, texture, and color, and classified taxonomically into soil orders based on observable properties such as organic matter content and degree of soil profile development (USDA-NRCS, 2010). The Natural Resources Conservation Service (NRCS) maintains soil maps on a county level for the entire U.S. and its territories.

Soybean is able to grow in a wide variety of soils, but grows best in a loose, well-drained loam (NSRL, 2013). Soybean requires a variety of macro- and micro-nutrients in the soil to produce optimum yield. Macro-nutrients include nitrogen, phosphorus, potassium, calcium, and sulfur; micro-nutrients required by soybean include iron, zinc, copper, boron, manganese, molybdenum, cobalt, and chlorine (NSRL, 2013). The availability of these macro- and micro-nutrients may be affected by pH. In general, soybean may be cultivated in soils with a wide range of pH values, though soybean grows best in slightly acidic soils (NSRL, 2013).

Land management practices for soybean production can affect soil quality. While management practices, such as tillage and the use of agronomic inputs (e.g., fertilizers and pesticides), can improve soil quality, they can also cause damage if not properly used. Several concerns relating to agricultural practices include increased erosion, soil compaction, degradation of soil structure, nutrient loss, increased salinity, change in pH, and reduced biological activity (USDA-NRCS, 2001).

2.2.2 Water Resources

The principal law governing pollution of the nation's water resources is the Federal Water Pollution Control Act of 1972, better known as the Clean Water Act (CWA). The Act utilizes water quality standards, permitting requirements, and monitoring to protect water quality. The EPA sets the standards for water pollution abatement for all waters of the United States under the programs contained in the CWA, but, in most cases, gives qualified States the authority to issue and enforce permits. Drinking water is protected under the Safe Drinking Water Act (SDWA) of 1974 (Public Law 93-523, 42 U.S.C. 300 *et seq*.).

Surface water in rivers, streams, creeks, lakes, and reservoirs supports everyday life by providing water for drinking and other public uses, irrigation, and industry (USGS, 2011). In 2005, about 77% of the freshwater used in the United States came from surface water sources, whereas the other 23% originated from groundwater (USGS, 2011). Groundwater is the water that fills cracks and other openings in beds of rocks and sand (USGS, 2009b). Each drop of rain that soaks into the soils moves downward to the water table, which is the water level in the groundwater reservoir.

Soybean production may directly affect water resources through the use of local water sources and indirectly through associated management practices, including tillage and the use of agricultural inputs. The typical amount of water required for a high-yielding soybean crop is approximately 20 inches during the growing season (Hoeft et al., 2000). While normal climatic conditions may provide sufficient water to produce a soybean crop, precipitation may vary across states and irrigation may be needed to supplement precipitation amounts. Irrigation may also vary from year to year. In general, however, the majority of soybean acreage in the United States is grown with very little supplemental irrigation (The Keystone Center, 2009). In 2006, approximately 8.6 percent of U.S. soybean acres (6,300, 000 acres out of 72,900,000 acres) were irrigated. The primary source of irrigation water for soybean is groundwater[10], comprising approximately 92 percent of irrigated soybean acres, compared to just 6.3 percent of irrigated soybean acres that used surface waters[11] a source in 2006 (Table 6).

Agricultural non-point source (NPS) pollution is the primary source of discharge pollutants to groundwater, flowing water (permanent or intermittent streams), or semi-static water (Ramanarayanan et al., 2005). NPS pollutants generally include agricultural inputs, such as

[10] The primary example of a groundwater source is an aquifer.
[11] Examples of surface water include flowing waters (streams and rivers) and semi-static waters (ponds, lakes, and reservoirs).

fertilizers or pesticides. Although meteorological (e.g., precipitation, temperature), morphological (e.g., land use, soil type), and environmental fate drivers affect water quality, anthropogenic practices (product use and management) are the most relevant, as this driver is generally under direct grower control on a soybean farm (Ramanarayanan et al., 2005). In particular, tillage practices often have a strong, indirect effect on water quality through the improvement of soil quality and water retention characteristics. Agricultural pollutants released by soil erosion include sediments, fertilizers, and pesticides that are introduced to area lakes and streams when they are carried off of fields by rain or irrigation waters (EPA, 2005).

Table 6. Soybean irrigation, 2006

	Units	Estimate
Planted acres	Acres	72,880,160
Irrigated acres	Acres	6,260,636
Surface water source	Percent of irrigated acres	6.279
Ground water source	Percent of irrigated acres	92.097
Water applied per irrigated acre	Inches	8.382

Source USDA-ERS (2013c)

2.2.3 Air Quality

The Clean Air Act (CAA) requires the maintenance of National Ambient Air Quality Standards (NAAQS). The NAAQS, developed by the EPA to protect public health, establishes limits for six criteria pollutants: ozone (O_3), nitrogen dioxide (NO_2), carbon monoxide (CO), sulfur dioxide (SO_2), lead (Pb), and inhalable particulates[12]. The CAA requires states to achieve and maintain the NAAQS within their borders. Each state may adopt requirements stricter than those of the national standard and each is required by the EPA to develop a State Implementation Plan (SIP) that contains strategies to achieve and maintain the national standard of air quality within the state. Areas that violate air quality standards are designated as non-attainment areas for the relevant pollutants, whereas areas that comply with air quality standards are designated as attainment areas.

Cultivation of soybean, like any other agricultural system, may affect air quality. Primary and common sources of emissions associated with crop production include exhaust from motorized equipment such as tractors and irrigation equipment, soil particulates from tillage and wind induced erosion, and particulates from burning of fields (Hoeft et al., 2000; Aneja et al., 2009; EPA, 2010b). Air emissions that are related to climate change are discussed in Subsection 2.2.4 – Climate Change.

Pesticide spraying may introduce air quality impacts from drift and volatization. Drift is the spatial movement of pesticides from an initial application site, either as particles, aerosols, or bound to dust (EPA, 2009c). Volatilization, while representing another route that leads to the off-site movement of a pesticide, occurs when the pesticide itself changes from a solid/liquid to a gas/vapor phase after initial application to soil and plant surfaces (EPA, 2009c). The off-site

[12] Inhalable particulates are defined as: 1) coarse particulate matter (PM) greater than 2.5 micrometers and less than 10 micrometers in diameter (PM_{10}); and 2) fine particles less than 2.5 micrometers in diameter ($PM_{2.5}$).

movement of pesticides, either through drift or volatization, may ultimately expose people, wildlife, plants, and the environment to pesticide residues that can cause health and environmental effects and property damage (EPA, 2009d).

Factors affecting drift and volatization include application equipment and method, weather conditions, topography, and the type of crop being sprayed (EPA, 2000). The EPA is currently evaluating new regulations for pesticide drift labeling and the identification of BMPs to control such drift (EPA, 2009d), as well as identifying scientific issues surrounding field volatility of conventional pesticides (EPA, 2010g).

2.2.4 Climate Change

Climate change represents a statistical change in global climate conditions, including shifts in the frequency of extreme weather (Cook et al., 2008; Karl et al., 2008). Agriculture is recognized as a direct (e.g., exhaust from equipment) and indirect (e.g., agricultural-related soil disturbance) source of greenhouse gas (GHG) emissions. Greenhouse gases, including carbon dioxide (CO_2), methane (CH_4), and nitrous oxide (N_2O), function as retainers of solar radiation (Aneja et al., 2009). The U.S. agricultural sector is identified as the second largest contributor to GHG emissions (EPA, 2010a).

Agriculture may also affect dynamic soil processes through tillage and other land management practices (Smith and Conen, 2004). In general, conservation tillage strategies are associated with more stable and increased carbon sequestration due to a net reduction in CO_2emissions (Lal and Bruce, 1999; West and Marland, 2002). Recent literature, however, suggests that the relationship between conservation tillage and increased carbon sequestration require more study, as soil depth level and seasonal sampling bias may inadvertently affect measurements (Potter et al., 1998; Baker et al., 2005). Additionally, the relationship between different GHG emissions, such as $CO_2$and N_2O may influence paradigms related to tillage strategies and global climate change (Gregorich et al., 2005). For example, increased N_2O emissions as a result of conservation tillage strategies may offset any gains achieved through increased carbon sequestration. Like the relationship between conservation tillage strategies and carbon sequestration, a broad generalization regarding the impact of tillage strategy and N_2O emissions is difficult, as numerous factors influence soil nitrification cycles, including geographic location, soil structure, moisture, and farm-level management practices (Grandy et al., 2006; Gregorich et al., 2006; Rochette et al., 2008).

Global climate change may also affect agricultural crop production (CCSP, 2009). These potential impacts on the agro-environment and individual crops may be direct, including changing patterns in precipitation, temperature, and duration of growing season, or may cause indirect impacts influencing weed and pest pressure (Rosenzweig et al., 2001; Schmidhuber and Tubiello, 2007). The impacts of GE crop varieties on climate change are unclear, though it is likely dependent on cropping systems, production practices, geographic distribution of activities, and individual grower decisions. APHIS will continue to monitor developments that may lead to possible changes in the typical production system likely to result from GE products brought to APHIS for a determination of nonregulated status. The potential impact of climate change on agricultural output, however, has been examined in more detail. A recent Intergovernmental Panel on Climate Change (IPCC) forecast (2007) for aggregate North American impacts on agriculture from climate change actually projects yield increases of 5 to 20 percent for this century. The IPCC report notes that certain regions of the U.S. will be more heavily impacted because water resources may be substantially reduced. While agricultural impacts on existing crops may be substantial, North American production is expected to adapt with improved cultivars and responsive farm management (IPPC, 2007).

2.3 Biological Resources

2.3.1 Animal Communities

Animal communities in this discussion include wildlife species and their habitats. Wildlife refers to both native and introduced species of mammals, birds, amphibians, reptiles, insects, and fish/shellfish. Wildlife species use a wide range of strategies to meet their needs from highly adaptable generalists to specialists that require a narrow set of conditions to survive (Bolen and Robinson, 2003). Wildlife may also occupy a wide array of habitats, including agricultural lands. Agriculture dominates human uses of land (Robertson and Swinton, 2005). In 2012, 914 million acres were devoted to farming, including: crop production, pasture, rangeland, Conservation Reserve Program, Wetlands Reserve Program, or other government program uses (USDA-NASS, 2013d). How these lands are maintained influences the function and integrity of ecosystems and the wildlife populations that they support.

For the purpose of this subsection, discussion is primarily limited to vertebrates that feed on soybean and invertebrates that may feed on or are found in soybean. Soybean fields, along with the majority of agricultural lands that produce commodity crops, are intensively cultivated lands that undergo periodic disturbances that make it less amendable to habitat establishment by vertebrates.

Deer and groundhogs feed on soybean and cause soybean damage, while feeding damage from Eastern cottontail, raccoon, squirrels, and other rodents is of less importance (MacGowan et al., 2006). Additionally, migratory birds may feed on spilled soybeans following harvest (Gamble et al., 2002; Galle et al., 2009).

A variety of insects may be found in a soybean field, ranging from pests that feed on soybean tissues to beneficial insects that provide valuable ecosystem services by preying on other soybean insect pests. Insect pests are considered less problematic than weeds in U.S. soybean production; nevertheless, insect injury can impact yield, plant maturity, and seed quality. A variety of insect pests may be found in U.S. soybean fields, including those that feed on reproductive tissue, foliage, and roots/nodules (Table 7).

Table 7. Common soybean insect pests

Common name (Scientific name)	
Pod, stem, and seed feeders	
Southern green stink bug (*Nezara viridula*)	Three-cornered alfalfa hopper (*Spissistilus festinus)*
Green stink bug (*Acrosternum hilare*)	Lesser cornstalk borer (*Elasmopalpus lignosellus*)

Common name (Scientific name)	
Brown Stink Bug (*Euschistus servus/Euschistus spp.*)	*Dectes* stem borer (*Dectes texanus taxanus*)
Bean leaf beetle (*Cerotoma trifurcata*)	Seed corn maggot (*Delia platura*)
Corn earworm (*Helicoverpa zea*)	
<u>Foliage feeders</u>	
Soybean looper (*Pseudoplusia includens*)	Two-spotted spider mite (*Tetranychus urticae*)
Velvetbean caterpillar (*Anticarsia gemmatalis*)	Mexican bean beetle (*Epilachna varivestis*)
Green cloverworm (*Plathypena scabra*)	Potato leafhopper (*Emopoasca fabae*)
Beet armyworm (*Spodoptera exigua*)	Silverleaf whitefly (*Bemisia argentifolii*)
Fall armyworm (*Spodoptera frugiperda*)	Bandedwinged whitefly (*Trialeurodes abutilonea*)
Yellow striped armyworm (*Spodoptera ornithogalli*)	Grasshopper (*Melanoplus spp.*)
Yellow woolybear (*Spilosoma virginica*)	Soybean thrips (*Neohydatothrips variabilis*)
<u>Root and nodule feeders</u>	
Soybean nodule fly (*Rivellia quadrifasciata*)	White grubs (*Phyllophaga spp.*)
Banded cucumber beetle (*Diabrotica balteata*)	Grape colaspis (*Colaspis brunnea*)

Source: Boethel (2004)

Insects such as the lady beetle (Coccinellidae), big-eyed bug (Lygaeidae), ground beetle (Carabidae), lacewing (Chrysopidae), damsel bug (Nabidae), insidious flower bug/minute pirate bug (Anthocoridae), assassin bug (Triatominae), spined soldier bug (Pentatomidae), and parasitoid wasps (e.g., Braconidae, Ichneumonidae), as well as a multitude of spiders (Order: Araneae) may benefit soybean production by preying on plant pests (Stewart et al., 2007; Iowa State University, No Date). Other, soil dwelling fauna such as earthworms and arthropods play critical roles in the aeration and turn-over of soil, processing of wastes and detritus, and nutrient cycling (ATTRA, 1999; USDA-NRCS, 2004).

2.3.2 Plant Communities

Soybean production in the United States encompasses a wide range of ecosystems and climate zones. The plant communities surrounding and within a soybean field may be varied and adapted to the local climate and soil, as well as the frequency of natural or human-induced disturbances (Smith and Smith, 2003). Consequently, the plant communities surrounding and within a soybean field may often be region dependent.

The vegetative landscape surrounding a soybean field varies with region; soybean fields may be surrounded by additional soybean varieties, other crops, or woodland/pasture/ grassland areas. Areas adjacent to soybean fields are often highly managed to minimize sources of weed and insect invasion, and reduce cover or perches from which other pests may easily feed on the crop (Pierce II et al., 2008).

The majority of the discussion in this subsection will focus on weeds that may be found in soybean fields. Weeds are simply plants growing in areas undesired by humans (Baucom and Holt, 2009). Weeds are the most important pest complex in agriculture and are represented by plants with specific characteristics that make these species uniquely adapted to agricultural environments (Gibson et al., 2005; Baucom and Holt, 2009). Plants that colonize frequently disturbed environments exhibit early germination and rapid growth from seedling to sexual maturity, have the ability to reproduce sexually and asexually and are well-adapted to agricultural fields (Baucom and Holt, 2009).

Weeds are perceived to be the most substantial pest problem in soybean production, negatively affecting yield through competition for light, nutrients, and moisture (Aref and Pike, 1998). Accordingly, as discussed in Subsection 2.1.2 – Agronomic Practices, the majority of agronomic inputs in soybean production are herbicides intended to control weed populations. If weeds are left to compete with soybean for the entire growing season, yield losses can exceed 75 percent (Dalley et al., 2001). Common weeds found in soybean fields through the United States include a variety of both grass and broadleaf plants (Table 8).

Table 8. Top 25 weeds targeted for control in U.S. soybean fields

Common Name	Acres Affected
Redroot pigweed	42,045,215
Common waterhemp	37,398,103
Lambsquarters	33,961,809
Velvetleaf	28,944,460
Foxtail	26,824,291
Marestail (horseweed)	22,540,757
Cocklebur	21,745,535
Giant ragweed	18,884,095
Ragweed	14,384,756
Yellow foxtail	13,853,453
Morningglory	12,364,841
Johnsongrass	12,303,265
Giant foxtail	10,683,419
Volunteer corn	9,659,925
Kochia	8,747,938
Grasses (all)	6,885,182
Green foxtail	6,775,745
Crabgrass	5,226,556
Sunflower	5,004,284
Barnyard grass	4,859,737
Henbit	4,651,447
Palmer’s amaranth	4,407,350
Quackgrass	3,445,238
Chickweed	3,385,915

Fall panicum	3,211,761

Source: Modified from (Heap, 2013)

Weed populations change in response to agricultural management decisions. Collectively, the management decisions related to cultivation of a crop will impart selection pressures on the present weed community, resulting in changes to weed shifts on a local level (i.e. field level). These weed shifts occur regardless of the selection pressure[13] and may represent changes in weed density and/or weed diversity (Reddy and Norsworthy, 2010; Weller et al., 2010). For example, in aggressive tillage systems, weed diversity tends to decline and annual grasses and broadleaf plants are the dominant weeds; however, in no-till fields, a greater diversity of annual and perennial weeds species may occur (Baucom and Holt, 2009). Weed shifts are generally most dramatic when a single or small group of weeds increases in abundance at the expense of other weed populations, potentially dictating the primary management efforts of the grower. At present, no group of weeds represents this shift better than the development and persistence of herbicide-resistant weeds, particularly glyphosate-resistant weeds.

Herbicide-Resistant Weeds

Weeds can develop resistance to herbicides for the following reasons: frequent exposure to a single herbicide, the spread of naturally-resistant weeds seeds, and the out-crossing of herbicide-resistant genes from plants (GE or naturally-resistant plants) to weedy relatives. The development of herbicide resistance in weeds is not unique to any one country (Figure 2), particular herbicide (Figure 3), or crop variety.

[13] Selection pressure may be defined as any event or activity that reduces the reproductive likelihood of an individual in proportion to the rest of the population of that one individual. In agriculture, selection pressure may be imparted by any facet of management in the production of a crop, including the type of crop cultivated, strategy of pest management, or when and how a crop is planted or harvested.

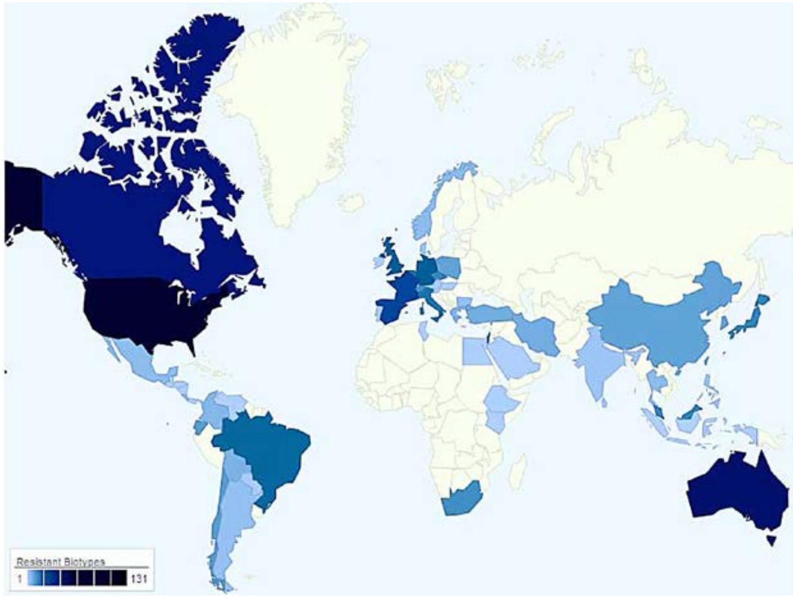


Figure 2. Global distribution of herbicide-resistant biotypes, 2010. Color intensity is associated with an increasing number of herbicide-resistant biotypes. Reproduced from Heap (2013).

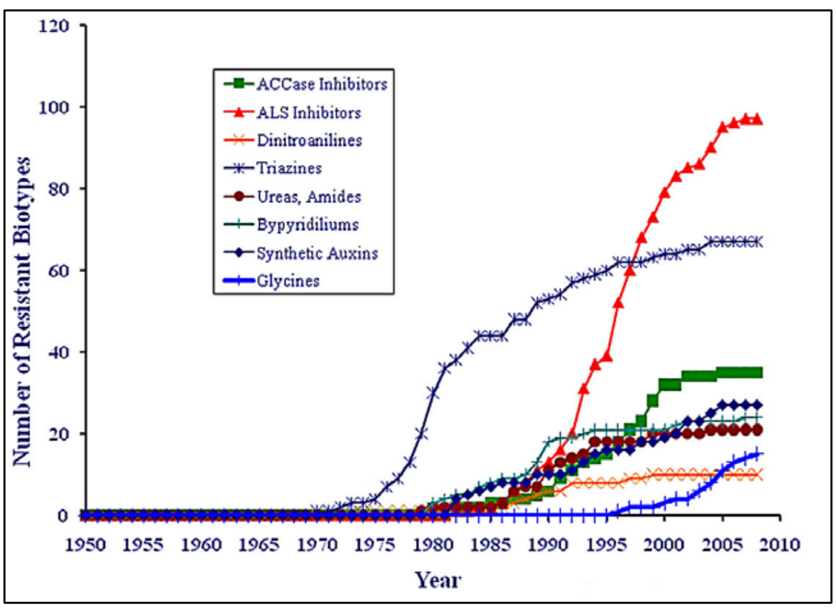


Figure 3. Global herbicide-resistant biotypes by mode of action, 1950 – 2010. Reproduced from Heap (2013).

Currently, there are 370 herbicide-resistant weed biotypes that have been reported, representing 200 species and infesting an estimated 570,000 fields globally (Heap, 2013). In the United States, 76 weed species have developed resistance to at least 17 herbicide MOAs (Heap, 2013).

Following the introduction of glyphosate-resistant crop varieties[14], glyphosate-resistant weed populations[15] developed and increased in abundance. As of January 2013, there are 24 weed species with evolved resistance to glyphosate world-wide and 14 in the U.S. (Table 9). In the United States, it is estimated that 10 of the 14 glyphosate-resistant weed species were identified in glyphosate-resistant crop systems and are widely distributed in regions where agriculture predominates. Many of the glyphosate-resistant weeds are agronomically important and dominant members of weed communities. For example, glyphosate-resistant Palmer pigweed (amaranth) is a major economic problem in the Southeast United States, while glyphosate-resistant waterhemp is an economically important weed in Midwestern states (Culpepper et al., 2006; Owen, 2008). Other glyphosate-resistant weeds of importance include giant ragweed, common lambs quarters, and horseweed (Owen, 2008; Owen et al., 2011b). Currently, ten glyphosate-resistant weeds have been identified in U.S. soybean fields, spanning 26 U.S. States (Figure 4).

Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska corn fields and two populations of Palmer amaranth in Kansas and Nebraska corn and sorghum fields were reported to be resistant to 4-HPPD inhibitors (Heap, 2013). While the two population of Palmer amaranth and three of the populations of common waterhemp were resistant to 4-HPPD inhibitors they were not specifically resistant to isoxaflutole. However, cross-family resistance to isoxaflutole may be possible. One example of this was found in 2011 in a common waterhemp biotype from Iowa that displayed cross-family resistance to 4-HPPD inhibitors and specifically to isoxaflutole (Heap, 2013).

Table 9. Glyphosate-resistant weeds in the U.S. as of January, 2013

System	Species	Year Identified
Weeds identified outside of Roundup Ready® Systems	Hairy Fleabane (*Conyza bonariensis*)	2007
	Italian Ryegrass (*Lolium multiflorum*)	2004
	Junglerice (*Echinochloa colona*)	2008
	Rigid Ryegrass (*Lolium rigidum*)	1998
Weeds identified in Roundup Ready® Systems	Annual Bluegrass (*Poa annua*)	2010
	Common Ragweed (*Ambrosia artemisiifolia*)	2004
	Common Waterhemp (*Amaranthus rudis*)	2005
	Giant Ragweed (*Ambrosia trifida*)	2004
	Goosegrass (*Eleusine indica*)	2010
	Horseweed, Marestail (*Conyza canadensis*)	2000
	Johnsongrass (*Sorghum halepense*)	2007
	Kochia (*Kochia scoparia*)	2007
	Palmer Amaranth (*Amaranthus palmeri*)	2005
	Spiny Amaranth (*Amaranthus spinosus*)	2012

Source: Heap (2013)

[14] Glyphosate-resistant soybean was introduced 1996; glyphosate-resistant cotton in 1997; and glyphosate-resistant corn in 1998 (USDA-APHIS, 2012).
[15] Weed populations and weed biotypes will be used interchangeably throughout this EA.

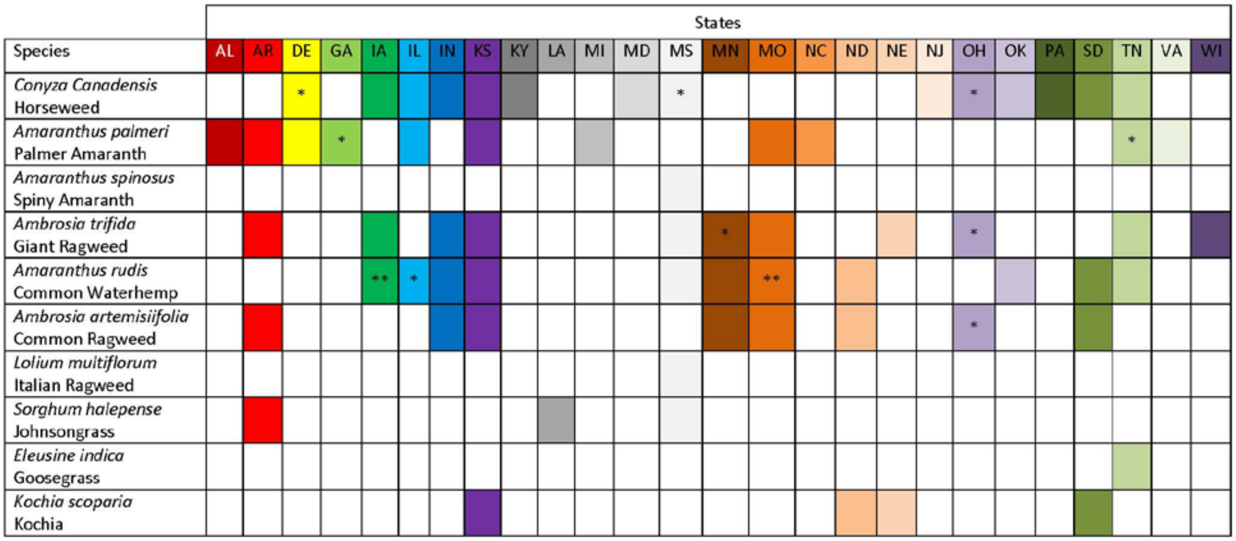


Figure 4. Glyphosate-resistant weeds in U.S. soybean production states and soybean fields. Note that presence of a population is unrelated to prevalence. * indicates at least one population in that states possesses resistance to glyphosate and another herbicide. **indicates at least one population in that state possesses resistance to glyphosate and two or more other herbicides. Source: Heap (2013)

2.3.3 Gene Flow and Weediness

Gene flow is a biological process that facilitates the production of hybrid plants, introgression of novel alleles into a population, and evolution of new plant genotypes. Gene flow to and from an agro-ecosystem can occur on both spatial and temporal scales. In general, plant pollen tends to represent the major reproductive method for moving across areas, while both seed and vegetative propagation tend to promote the movement of genes across time and space.

The rate and success of gene flow is dependent on numerous factors. General factors related to pollen-mediated gene flow include the presence, abundance, and distance of sexually-compatible plant species; overlap of flowering phenology between populations; the method of pollination; the biology and amount of pollen produced; or weather conditions, including temperature, wind, and humidity (Zapiola et al., 2008). Seed-mediated gene flow also depends on many factors, including the absence, presence, and magnitude of seed dormancy; contribution and participation in various dispersal pathways; or environmental conditions and events (Zapiola et al., 2008).

Soybean is a plant species with perfect flowers[16] (Figure 5). Due to this reproductive biology, soybean is generally considered a self-pollinating species (OECD, 2010), though small levels of insect-mediated pollination may occur (USDA-APHIS, 2012d).

[16] Perfect flowers are those flowers that possess both male (stamens) and female (pistil) organs; this is in contrast to imperfect flowers, where male and female organs are spatially segregated in separate flowers.

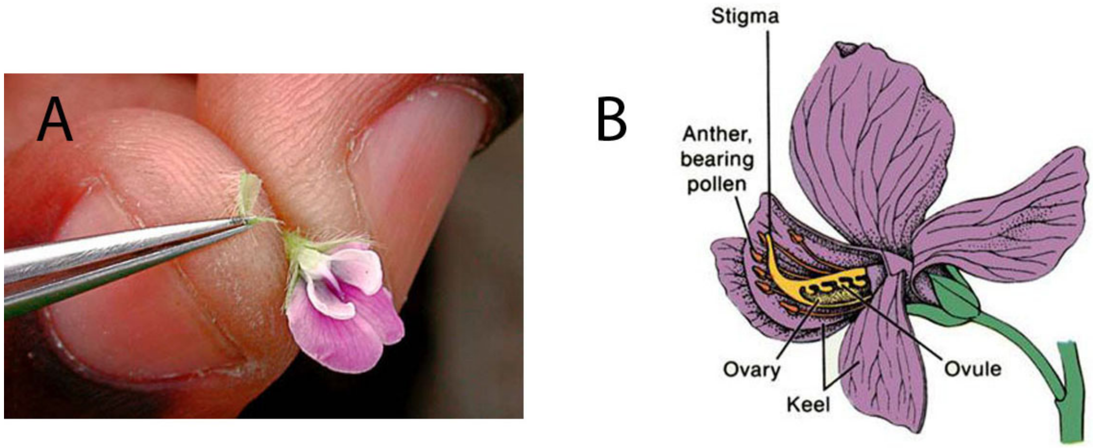


Figure 5. Soybean floral morphology.
(A) Soybean flower and (B) diagram of a soybean flower, showing male and female reproductive tissues. Sources: (A) Plant & Soil Science eLibrary (2013) and (B) UCA (2013).

Soybean is not native to the United States and there are no feral or weedy relatives. Consequently, soybean in the United States can cross only with other soybean varieties. Additionally, potential of soybean weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (Raper and Kramer, 1987).

2.3.4 Microorganisms

Soil microorganisms play a key role in soil structure formation, decomposition of organic matter, toxin removal, nutrient cycling, and most biochemical soil processes (Garbeva et al., 2004). They also suppress soil-borne plant diseases and promote plant growth (Doran et al., 1996). The main factors affecting microbial population size and diversity include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Garbeva et al., 2004). Plant roots, including those of soybean, release a variety of compounds into the soil creating a unique environment for microorganisms in the rhizosphere. Microbial diversity in the rhizosphere may be extensive and differs from the microbial community in the bulk soil (Garbeva et al., 2004).

2.3.5 Biodiversity

Biodiversity refers to all plants, animals, and microorganisms interacting in an ecosystem (Wilson, 1988). Biodiversity provides valuable genetic resources for crop improvement and also provides other functions beyond food, fiber, fuel, and income (Harlan, 1975). These include pollination, genetic introgression, biological control, nutrient recycling, competition against natural enemies, soil structure, soil and water conservation, disease suppression, control of local microclimate, control of local hydrological processes, and detoxification of noxious chemicals (Altieri, 1999). The loss of biodiversity results in a need for costly management practices in order to provide these functions to the crop (Altieri, 1999).

The degree of biodiversity in an agroecosystem depends on four primary characteristics: 1) diversity of vegetation within and around the agroecosystem, 2) permanence of various crops within the system, 3) intensity of management, and 4) extent of isolation of the agroecosystem from natural vegetation (Southwood and Way, 1970).

Agricultural land subject to intensive farming practices, such as that used in crop production, generally has low levels of biodiversity compared with adjacent natural areas. Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest limits the diversity of plants and animals (Lovett et al., 2003).

Since biological diversity can be defined and measured in many ways, APHIS considers determining the level of biological diversity in any crop to be complex and difficult to achieve concurrence. Another complication with biodiversity studies is separating expected impacts from indirect impacts. For example, reductions of biological control organisms are seen in some Bt-expressing GE crops, but are caused by reductions of the pest host population following transgenic pesticide expression in the transformed crop plant.

2.4 Public Health

2.4.1 Human Health

The general population of the United States is most likely to consume soybean products[17] or consume foods containing or prepared with soybean oil. Human health concerns surrounding GE soybean primarily involve the consumption of GE soybean products. In particular, human health concerns surrounding GE soybeans relate to the composition of the GE soybean itself, including potential toxicity or allergenicity of the introduced proteins, and any pesticides that may remain on the GE soybean product as a result of standard cultivation practices.

With regard to the general safety of the soybean itself, under the FFDCA, it is the responsibility of food and feed manufacturers to ensure that the products they market are safe and properly labeled. Food and feed derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE soybean for food and feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food. The FDA evaluates the submission and responds to the developer by letter (FDA, 2012b).

As noted by the National Research Council (NRC), unexpected and unintended compositional changes arise with all forms of genetic modification, including both conventional hybridizing and genetic engineering (NRC, 2004). The NRC also noted that at the time, no adverse health effects attributed to genetic engineering had been documented in the human population. Reviews on the nutritional quality of GE foods have generally concluded that there are no

[17] Soybean products include processed foods, like tofu, tempeh, miso, or soy sauce. Soybean products may also include fresh foods, such as edamame, mukimame, soynuts, and soy sprouts.

significant nutritional differences in conventional versus GE plants for food or animal feed (Faust, 2002; Flachowsky et al., 2005).

As previously described in Subsection 2.1.2 – Agronomic Practices, pesticide use is common on a conventional soybean field. In particular, herbicide use is widespread and common (USDA-NASS, 2007a). The widespread and common use of pesticides may result in small amounts (called residues) in or on soybean and soybean products. To ensure safety of the soybean food supply, the EPA regulates the amount of each pesticide that may remain in or on foods. These limits, called tolerances, are established to ensure food safety and are the result of the EPA making a safety finding that "the pesticide can be used with reasonable certainty of no harm." (EPA, 2013f). This finding of reasonable certainty of no harm is obligated under the FFDCA, as amended by the Food Quality Protection Act of 1996 (FQPA). In addition, the FDA and the USDA monitor foods for pesticide residues and work with the EPA to enforce these tolerances (see(USDA-AMS, 2013). In setting pesticide tolerances, the EPA generally will consider (EPA, 2013f):

- The toxicity of the pesticide and its break-down products;
- How much the pesticide is applied to the crop and how often; and
- How much of the pesticide (i.e., the residue) remains in or on food by the time is it marketed and prepared.

Pesticide tolerance levels for glyphosate and isoxaflutole have been established for a wide variety of commodities, including soybean (EPA, 2012d). For glyphosate, the tolerance for soybean seed is 20 parts per million (ppm) (EPA, 2012c), while the established tolerance of isoxaflutole is 0.05 ppm (EPA, 2012c).

2.4.2 Worker Health

Agricultural workers are the segment of the population most likely to encounter risks related to soybean production. Worker hazards in farming are common to all types of agricultural production, and include hazards of equipment and plant materials. Pesticide application represents the primary exposure route to pesticides for farm workers. However, common farm practices, training, and specialized equipment can mitigate exposure to pesticides by farm workers (Baker et al., 2005). For example, choosing from less toxic groups of insecticides to control soybean insects is a good common agricultural practice.

All pesticides sold or distributed in the U.S. must be registered by the EPA (EPA, 2013b). Registration decisions are based on scientific studies that assess the chemical's potential toxicity and environmental impact. To be registered, a pesticide must be able to be used without posing unreasonable risks to people or the environment. All pesticides registered prior to November 1, 1984, such as glyphosate, must also be reregistered to ensure that they meet the current, more stringent standards and have a reregistration review every 15 years (EPA, 2013b). Glyphosate was first registered in the U.S. in 1974; the latest reregistration decision for glyphosate was issued in 1993 (EPA, 1993; EPA, 2009a; EPA, 2009e). It is currently under reregistration review, which began in July 2009 and is scheduled for completion in 2015 (EPA, 2009a). Isoxaflutole was first registered in the U.S. in 1998; the most recent isoxaflutole ecological risk assessment was conducted in April 2010 for use on soybeans (EPA, 2011b). It is currently under reregistration review, which began in June 2011 and is scheduled for completion in 2017 (EPA, 2011b).

The EPA's Worker Protection Standard (WPS) (40 CFR part 170) was published in 1992 requiring actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protection to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance. Furthermore, the Occupational Safety and Health Administration require all employers to protect their employees from hazards associated with pesticides and herbicides.

Growers are required to use pesticides consistent with the application instructions provided on the EPA-approved pesticide labels. For example, pesticide labels specify the appropriate worker safety practices that must be followed, including the necessary PPE to be worn by mixers, loaders, other applicators and handlers. These label restrictions carry the weight of law and are enforced by the EPA and the states (FIFRA 7 U.S.C. 136j (a)(2)(G) Unlawful Acts).

2.5 Animal Feed

Soybean meal is a substantial part of animal feed rations in the United States. In 2011, approximately 39 million tons of soybean meal were produced, 27.3 million tons of which were marketed for animal feed, with the largest volumes consumed by poultry (48 percent), swine (26 percent), and beef (12 percent) (Soy Stats, 2012a). Like human health concerns, animal feed concerns surrounding GE soybean primarily involve consumption of GE soybean products and any remaining pesticide residues that may remain on GE soybean products.

Similar to the regulatory control for direct consumption of soybean under the FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from GE soybean must comply with all applicable legal and regulatory requirements, which are designed to protect human health. To help ensure compliance, a voluntary consultation process with FDA may be implemented before release of GE plants in animal feed into the market.

Although a voluntary process, thus far all applicants who wish to commercialize a GE variety that will be included in the food supply have completed a consultation with the FDA. In a consultation, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food and then submits to FDA a summary of its scientific and regulatory assessment of the food (FDA, 2012b). The FDA evaluates the submission and responds to the developer by letter.

As previously described in subsection 2.4.1 – Human Health, the EPA is responsible for regulating the amount of each pesticide that may remain in or on foods, thus ensuring safety of the soybean food supply. This responsibility is equally applicable to animal feed as it is to food. These limits, called tolerances, are established to ensure food safety and are the result of the EPA making a safety finding that "the pesticide can be used with reasonable certainty of no harm." (EPA, 2013f). This finding of reasonable certainty of no harm is obligated under the FFDCA, as amended by the FQPA of 1996. Similar to the establishment of pesticide tolerances for food, the EPA generally will consider the toxicity of the pesticide and its break-down products; how much the pesticide is applied to the crop and how often; and how much of the pesticide (i.e., the residue) remains in or on food by the time is it marketed and prepared in its establishment of tolerance for animal feed (EPA, 2013f).

2.6 Socioeconomic

2.6.1 Domestic Economic Environment

In 2012, 77 million acres of soybeans were cultivated in the United States (USDA-NASS, 2012b), yielding approximately 3.0 billion bushels at a value of 43.2 billion U.S. dollars (USDA-NASS, 2013h). Total 2012 U.S. inventory (2011 remaining stocks plus 2012 production) totaled 3.2 billion bushels, with 43 percent of U.S. soybean destined for the export market (USDA-ERS, 2012b). The remaining 57 percent of U.S. soybean inventory was primarily utilized to produce soybean meal for feed, with lesser amounts processed for soybean oil for industrial or consumption purposes; seed and residuals; or ending stock for storage. The majority of soybean in the United States is used to produce animal feed or secondary industrial products, with only a small proportion of the soybean crop being consumed directly by humans (GINA, 2011).

The domestic soybean industry is primarily composed of commodity production businesses and the users of soybean products (Figure 6). Ultimately, the profitability of a soybean field is dependent on the suitability of a soybean harvest for its target market and the production costs for that particular harvest.

Because domestic utilization of soybean is focused on animal feed and oil production, the chemical composition of a soybean at harvest is important. Soy meal typically contains about 50 percent protein by dry weight, and is the most important product of soybean production. Of the domestically crushed soybean, 53 percent of soybean by weight produces meal and 19 percent produces oil (USB, 2011a). Changes in fatty acid profile may impact food and industrial uses of the soybean oil. Fatty acid composition of the soybean oil affects melting point, oxidative stability, and chemical functionality, and changes in any of these can impact the market sector of the product (APAG, 2011). These fatty acid properties influence the market applications for the oil, and various foods and industrial products are formulated to take these properties into consideration (Cahoon, 2003; Cargill, 2011; Soy Connection, 2011).

Gross value of production on a typical U.S. soybean farm in 2011 was approximately $525/acre (Table 10). However, this does not take into associated production costs, such as operating costs and allocated overhead costs. In general, operating costs represented 26% ($137/acre) of soybean farm gross income and may include expenses related to seed purchases, agronomic inputs (e.g., fertilizers, irrigation, and pesticides), and the maintenance of farm equipment. Allocated overhead costs, on the other hand, represented approximately 49% ($260/acre) of soybean farm gross income and include expenses related to labor, acquisition of farming equipment, land rental rates, taxes, and insurance premiums. In total, net profit of a typical U.S. soybean farm, minus operating and overhead costs, was $129/acre in 2011 (USDA-ERS, 2012c).

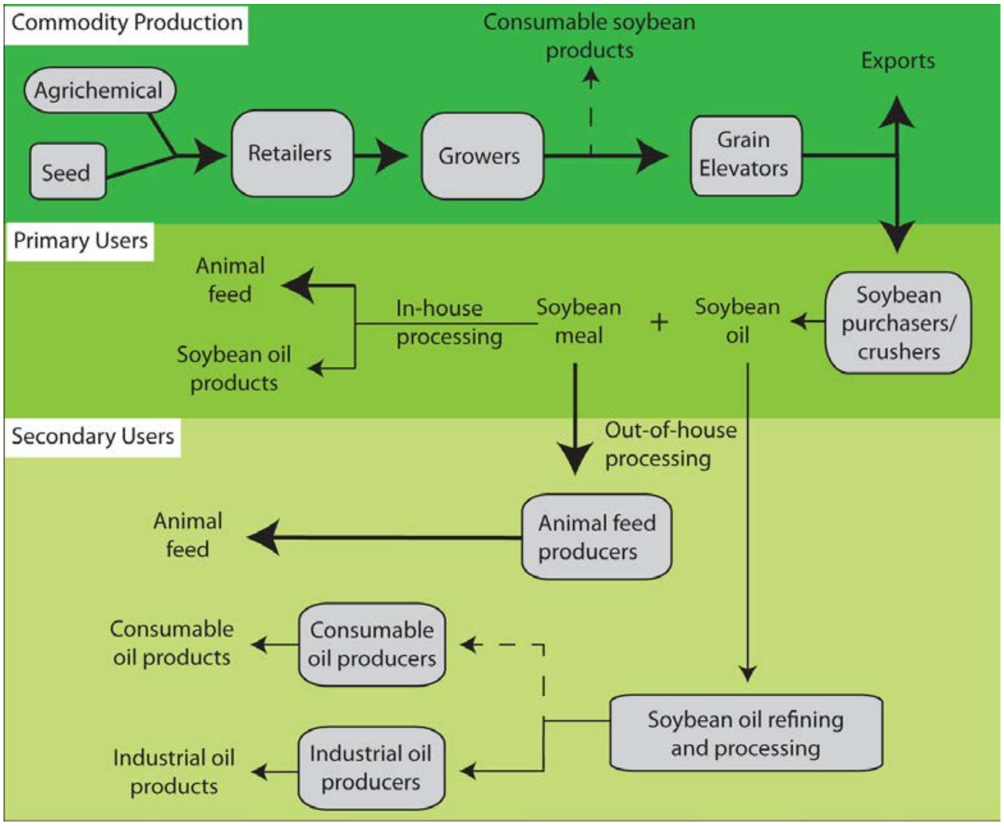


Figure 6. General flow of U.S. soybean commodities.
Size of directional arrows is approximately proportional to use. For example, bold arrows represent the primary path of soybean commodities, whereas dashed arrows represent paths of soybean use that are relatively minor. Businesses are boxed in gray, while commodities are unboxed.

Table 10. Soybean commodity costs and returns, 2011.

Gross value of production	**(dollars)**
Primary Product	525.36
Total, gross value of production	525.36
Operating costs:	**(dollars)**
Seed	55.55
Fertilizer	22.84
Chemicals	16.42
Custom operations	7.18
Fuel, lube, and electricity	20.98
Repairs	13.68
Purchased irrigation water	0.15
Interest on operating capital	0.07
Total, operating costs	136.87

Allocated overhead	**(dollars)**
Hired labor	2.07
Opportunity cost of unpaid labor	17.09
Capital recovery of machinery and equipment	81.34
Taxes and insurance	134.30
General farm overhead	9.93
Total, allocated overhead	15.10
Total costs listed	**(dollars)**
	259.83
Value of production less total costs listed	128.66
Value of production less operating costs	388.49

Source: USDA-ERS (2012c)

Organic Soybean Production

In the United States, only products produced using specific methods and certified under the USDA's Agricultural Marketing Service (AMS) National Organic Program (NOP) definition of organic farming can be marketed and labeled as "organic" (USDA-AMS, 2010). Organic certification is a process-based certification, not a certification of the end product; the certification process specifies and audits the methods and procedures by which the product is produced.

In accordance with NOP, an accredited organic certifying agent conducts an annual review of the certified operation's organic system plan and makes on-site inspections of the certified operation and its records. Organic growers must maintain records to show that production and handling procedures comply with USDA organic standards.

The NOP regulations preclude the use of excluded methods. The NOP provides the following guidance under 7 CFR Section 205.105:

> …to be sold or labeled as "100 percent organic", "organic" or "made with organic (specified ingredients or group(s))," the product must be produced and handled without the use of:…
>
> (a) Synthetic substances and ingredients,…
>
> (e) Excluded methods,…

Excluded methods are then defined at 7 CFR Section 205.2 as:

> A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macro-encapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Organic farming operations, as described by the NOP, are required to have distinct, defined boundaries and buffer zones to prevent unintended contact with excluded methods from adjoining land that is not under organic management. Organic production operations must also develop and maintain an organic production system plan approved by their accredited certifying agent. This plan enables the production operation to achieve and document compliance with the National Organic Standards, including the prohibition on the use of excluded methods (USDA-AMS, 2010).

Common practices organic growers may use to exclude GE products include planting only organic seed, planting earlier or later than neighboring farmers who may be using GE crops so that the crops will flower at different times, and employing adequate isolation distances between the organic fields and the fields of neighbors to minimize the chance that pollen will be carried between the fields (NCAT, 2003). Although the National Organic Standards prohibit the use of excluded methods, they do not require testing of inputs or products for the presence of excluded methods. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of the National Organic Standards (USDA-AMS, 2010). The current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in an organic-labeled product. The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan (Ronald and Fouce, 2006; USDA-AMS, 2010).

Organic soybean production represents an extremely small share of U.S. soybean production. In 2011, there were approximately 96,000 acres of organic soybean produced across 1,203 farms in the United States (USDA-NASS, 2012a). This represented about 0.13 percent of total U.S. soybean production in 2011 (USDA-NASS, 2011b; USDA-NASS, 2012a).

2.6.2 Trade Economic Environment

The United States produces approximately 33 percent of the global soybean supply(Soy Stats, 2012b). In 2011, the U.S. exported 1.3 billion bushels of soybean, which accounted for 37 percent of the world's soybean exports. In total, the U.S. exported $30.7 billion worth of soybean and soybean products globally in 2012 (Soy Stats, 2011; USDA-FAS, 2013). China is the largest export market for U.S. soybean with purchases totaling $15.2 billion. Mexico is the second largest export market with sales of $2.7 billion in the same year (Table 11). Other important markets include Japan and the EU.

Table 11. U.S. export markets for soybean and soybean products.

Top Ten U.S. Export Customers 2012*					
Soybean Exports		Soybean Meal Exports		Soybean Oil Exports	
China	14,973	Mexico	654	China	265
Mexico	1,862	Philippines	599	Mexico	209
Japan	1,127	Canada	485	Morocco	162
Indonesia	994	Venezuela	348	India	96
Germany	867	Ecuador	258	Nicaragua	60
Taiwan	768	Morocco	218	Venezuela	54
Egypt	739	Egypt	212	Canada	39
Turkey	457	Dominican Republic	194	Colombia	34
Thailand	407	Guatemala	150	Jamaica	32
South Korea	395	Japan	149	Domican Republic	27
Other	2,116	Other	1,589	Other	181
Total	24,705	Total	4,856	Total	1,159

*Values of exports are listed in millions of dollars
Source: (USDA-FAS, 2013)

3 ALTERNATIVES

This document analyzes the potential environmental consequences of a determination of nonregulated status of FG72 soybean. To respond favorably to a petition for nonregulated status, APHIS must determine that FG72 soybean is unlikely to pose a plant pest risk. APHIS has concluded through a PPRA that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012d). Therefore, APHIS must determine that FG72 soybean is no longer subject to 7 CFR part 340 or the plant pest provisions of the Plant Protection Act.

Two alternatives are evaluated in this EA: (1) No Action: Continuation as a Regulated Article and (2) Preferred Alternative: Determination that FG72 Soybean is No Longer a Regulated Article. APHIS has assessed the potential for environmental impacts for each alternative in the Environmental Consequences section.

3.1 No Action Alternative: Continuation as a Regulated Article

Under the No Action Alternative, APHIS would deny the petition. FG72 soybean and progeny derived from FG72 soybean would continue to be regulated articles under the regulations at 7 CFR part 340. Permits issued or notifications acknowledged by APHIS would still be required for introductions of FG72 soybean and measures to ensure physical and reproductive confinement would continue to be implemented. APHIS might choose this alternative if there were insufficient evidence to demonstrate the lack of plant pest risk from the unconfined cultivation of FG72 soybean.

This alternative is not the Preferred Alternative because APHIS has concluded through a PPRA that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012d). Choosing this alternative would not satisfy the purpose and need of making a determination of plant pest risk status and responding to the petition seeking nonregulated status.

3.2 Preferred Alternative: Determination that FG72 Soybean is No Longer a Regulated Article

Under this alternative, FG72 soybean and progeny would no longer be regulated articles under the regulations at 7 CFR part 340. FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012d). Permits issued or notifications acknowledged by APHIS would no longer be required for introductions of FG72 soybean and progeny derived from this event. This alternative best meets the purpose and need to respond appropriately to a petition seeking nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. Because the agency has concluded that FG72 soybean is unlikely to pose a plant pest risk, a determination of nonregulated status of FG72 soybean is a response that is consistent with the plant pest provisions of the Plant Protection Act, the regulations codified in 7 CFR part 340, and the biotechnology regulatory policies in the Coordinated Framework.

Under this alternative, growers may have future access to FG72 soybean and progeny derived from this event if the developer decides to commercialize FG72 soybean.

3.3 Alternatives Considered But Rejected from Further Consideration

APHIS assembled a list of alternatives that might be considered for FG72 soybean. The agency evaluated these alternatives with respect to the agency's authority under the plant pest provisions of the Plant Protection Act, and the regulations at 7 CFR part 340, with respect to environmental safety, efficacy, and practicality to identify which alternatives would be further considered for FG72 soybean. Based on this evaluation, APHIS rejected several alternatives. These alternatives are discussed briefly below along with the specific reasons for rejecting each.

3.3.1 Prohibit Any FG72 Soybean from Being Released

In response to public comments that stated a preference that no GE organisms enter the marketplace, APHIS considered prohibiting the release of FG72 soybean, including denying any permits associated with the field testing. APHIS determined that this alternative is not appropriate given that APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012d).

In enacting the Plant Protection Act, Congress found that

> [D]ecisions affecting imports, exports, and interstate movement of products regulated under [the Plant Protection Act] shall be based on sound science…§ 402(4).

On March 11, 2011, in a Memorandum for the Heads of Executive Departments and Agencies, the White House Emerging Technologies Interagency Policy Coordination Committee developed broad principles, consistent with Executive Order 13563, to guide the development and implementation of policies for oversight of emerging technologies (such as genetic engineering) at the agency level. In accordance with this memorandum, agencies should adhere to Executive Order 13563 and, consistent with that Executive Order, the following principle, among others, to the extent permitted by law, when regulating emerging technologies:

> "[D]ecisions should be based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each agency"

Based on the PPRA (USDA-APHIS, 2012d) and the scientific data evaluated therein, APHIS concluded that FG72 soybean is unlikely to pose a plant pest risk. Accordingly, there is no basis in science for prohibiting the release of FG72 soybean.

3.3.2 Approve the Petition in Part

The regulations at 7 CFR 340.6(d)(3)(i) state that APHIS may "approve the petition in whole or in part." For example, a determination of nonregulated status in part may be appropriate if there is a plant pest risk associated with some, but not all lines described in a petition. Because APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk, there is no regulatory basis under the plant pest provisions of the Plant Protection Act for considering approval of the petition only in part.

3.3.3 Isolation Distance between FG72 and Non-GE Soybean Production and Geographical Restrictions

In response to public concerns of gene movement between GE and non-GE plants, APHIS considered requiring an isolation distance separating FG72 soybean from non-GE soybean production. However, because APHIS has concluded that FG72 soybean is unlikely to pose a plant pest risk (USDA-APHIS, 2012d), an alternative based on requiring isolation distances would be inconsistent with the statutory authority under the plant pest provisions of the Plant Protection Act and regulations in 7 CFR part 340.

APHIS also considered geographically restricting the production of FG72 soybean based on the location of production of non-GE soybean in organic production systems or production systems for GE-sensitive markets in response to public concerns regarding possible gene movement between GE and non-GE plants. However, as presented in APHIS' PPRA for FG72 soybean, there are no geographic differences associated with any identifiable plant pest risks for FG72 soybean (USDA-APHIS, 2012d). This alternative was rejected and not analyzed in detail because APHIS has concluded that FG72 soybean does not pose a plant pest risk, and will not exhibit a greater plant pest risk in any geographically restricted area. Therefore, such an alternative would not be consistent with APHIS' statutory authority under the plant pest provisions of the Plant Protection Act and regulations in Part 340 and the biotechnology regulatory policies embodied in the Coordinated Framework.

Based on the foregoing, the imposition of isolation distances or geographic restrictions would not meet APHIS' purpose and need to respond appropriately to a petition for nonregulated status based on the requirements in 7 CFR part 340 and the agency's authority under the plant pest provisions of the Plant Protection Act. However, individuals might choose on their own to geographically isolate their non-GE soybean production systems from FG72 soybean or to use isolation distances and other management practices to minimize gene movement between soybean fields. Information to assist growers in making informed management decisions for FG72 soybean is available from the Association of Official Seed Certifying Agencies (AOSCA, 2010).

3.3.4 Requirement of Testing for FG72 Soybean

During the comment periods for other petitions for nonregulated status, some commenters requested USDA to require and provide testing for GE products in non-GE production systems. APHIS notes there are no nationally-established regulations involving testing, criteria, or limits of GE material in non-GE systems. Such a requirement would be extremely difficult to implement and maintain. Additionally, because FG72 soybean does not pose a plant pest risk (USDA-APHIS, 2012d), the imposition of any type of testing requirements is inconsistent with the plant pest provisions of the Plant Protection Act, the regulations at 7 CFR part 340 and biotechnology regulatory policies embodied in the Coordinated Framework. Therefore, imposing such a requirement for FG72 soybean would not meet APHIS' purpose and need to respond appropriately to the petition in accordance with its regulatory authorities.

3.4 Comparison of Alternatives

Table 12 presents a summary of the potential impacts associated with selection of either of the alternatives evaluated in this EA. The impact assessment is presented in Section 4 of this EA.

Table 12. Summary of issues of potential impacts and consequences of alternatives.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Meets Purpose and Need and Objectives	**No**	**Yes**
Unlikely to pose a plant pest risk	Satisfied through use of regulated field trials	Satisfied – risk assessment (USDA-APHIS, 2012d)
Management Practices		
Acreage and range of soybean production	93% of all soybean produced in US are GE herbicide-resistant varieties. Soybean total acreage is likely to remain steady.	Unchanged from No Action Alternative
Agronomic practices	Crop rotation can reduce selection pressure for weed resistance to herbicides. Reduced or conservation tillage has largely replaced conventional tillage.	Unchanged from No Action Alternative
Pesticide use	EPA-approved uses of glyphosate on soybean have been reviewed since the introduction of glyphosate resistant varieties, and have remained unchanged. Isoxaflutole underwent an ecological risk assessment in April 2010 for use on soybeans.	Isoxaflutole use on soybean is predicted to increase, but remain below an adoption rate of 5 percent of U.S. soybean acres.
Organic soybean production	Specialty crop growers employ practices and standards for seed production, cultivation, and product handling and processing to ensure that their products are not pollinated by or commingled with conventional or GE crops. Certified organic soybean acreage is a small but increasing percentage of overall soybean production.	Unchanged from No Action Alternative
Environment		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Soil quality	Agronomic practices such as crop type, tillage, and pest management can affect soil quality. Growers will adopt management practices to address their specific needs in producing soybean	Unchanged from No Action Alternative
Water resources	The primary cause of agricultural NPS pollution is increased sedimentation from soil erosion, which can introduce sediments, fertilizers, and pesticides to nearby lakes and streams. Agronomic practices such as conservation tillage, crop nutrient management, pest management, and conservation buffers help protect water quality from agricultural runoff	Unchanged from No Action Alternative
Air quality	Agricultural activities such as burning, tilling, harvesting, spraying pesticides, and fertilizing, including the emissions from farm equipment, can directly affect air quality. Aerial application of herbicides may impact air quality from drift, diffusion, and volatilization of the chemicals, as well as motor vehicle emissions from airplanes or helicopters.	Unchanged from No Action Alternative
Climate change	Agriculture-related activities are recognized as both direct sources of greenhouse gases (GHGs) (e.g., exhaust from motorized equipment) and indirect sources (e.g., agriculture-related soil disturbance, fertilizer production)	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Animal communities	Invertebrates that feed on soybean are typically considered pests and may be controlled by the use of insecticides or other production practices. The toxicity of glyphosate to animal species from registered uses poses minimal risks to animals. EPA concluded that the level of concern for acute and chronic risks for birds, mammals, and fish was not exceeded as a result of isoxaflutole application	Unchanged from No Action Alternative
Plant communities	Soybean fields can be bordered by other agricultural fields (including other soybean varieties), woodlands, or pasture and grasslands. The most agronomically important members of a surrounding plant community are those that behave as weeds. Soybean growers use production practices to manage weeds in and around fields.	Unchanged from No Action Alternative
Gene flow/weediness	Cultivated soybean varieties can cross pollinate. Growers use various production practices to limit undesired cross pollination.	Unchanged from No Action Alternative
Soil microorganisms	APHIS has previously examined potential impacts of glyphosate on microorganisms in soils of field under cultivation with HR crops, and has not found evidence linking applications of glyphosate to changes in soil microbial communities that have adverse effects on plants grown in those soils. Isoxaflutole is readily degraded in soil by soil microorganisms. No long term effects on soil microorganisms were identified with isoxaflutole use.	Unchanged from No Action Alternative

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Biodiversity	HR crops, such as soybean, have been correlated with an increase in conservation tillage in U.S. crop production, which promotes biodiversity by allowing the establishment of other plants, and the accumulation of more plant residue that increases soil organic matter, food, and cover for wildlife. Effects of GE crops have been associated with positive impacts on biodiversity because of increased yields, fewer applications of less toxic pesticides, and facilitation of conservation tillage.	Unchanged from No Action Alternative
Human and Animal Health		

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Human/worker health	2mEPSPS and HPPD W336 proteins pose no potential for toxicity or allergenicity for humans. Agricultural workers that routinely handle glyphosate may be exposed during spray operations. Because of low acute toxicity of glyphosate, absence of evidence of carcinogenicity and other toxicological concerns, occupational exposure data is not required for reregistration. However, EPA has classified some glyphosate formulations as eye and skin irritants. Isoxaflutole also exhibits low acute toxicity but is classified as "likely to be a human carcinogen however, EPA has determined no harm to human health will result from aggregate exposure to isoxaflutole or its residues. The EPA's Worker Protection Standard (WPS) (EPA, 1992); 40 CFR Part 170.1, *Scope and Purpose*) requires employers to take actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.	A comprehensive assessment of the safety of 2mEPSPS and HPPD W336 demonstrated that the proteins are nontoxic to mammals and unlikely to be a food allergen. EPA-registered pesticides that are currently used for soybean production would continue to be used by growers under the Preferred Alternative. Agricultural production with FG72 soybean does not require any change to the agronomic practices or chemicals currently used (i.e., pesticides) for conventional soybean. Therefore, worker safety issues associated with the agricultural production of FG72 soybean would remain the same as those under the No Action Alternative.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Livestock health/animal feed	Processed soybeans are the largest source of protein in animal feed. EPSPS proteins are not expected to be allergenic, toxic, or pathogenic in mammals or poultry. The maximum tolerance level for glyphosate in soybean is 20 ppm for grain and is 100 ppm for forage. The maximum tolerance level for Isoxaflutole in soybean is 0.05 ppm for grain and is 0.3 ppm for seed and grain, aspirated fractions.	A compositional analysis concluded that forage and grain from FG72 soybean hybrids are considered similar in composition to forage and grain from both the non-transgenic comparator and conventional soybean hybrids. Therefore this is unchanged from the No Action Alternative
Socioeconomic		
Domestic economic environment	The widespread adoption of herbicide-resistant soybean has been attributed to the cost savings for production, among other non-monetary benefits.	Under the preferred alternative, growers would have an additional tool to use against glyphosate resistant weeds (isoxaflutole) which may reduce economic loss.

Attribute/Measure	Alternative A: No Action	Alternative B: Determination of Nonregulated Status
Trade economic environment	The primary US soybean export destinations are also the largest world importers of soybean and do not have major barriers for importing food or feed commodities produced from transgenic crops, including those with herbicide resistance traits. Nevertheless, import of each specific trait requires separate application and approval by the importing country	The trade economic impacts associated with a determination of nonregulated status of FG72 soybean are anticipated to be similar to the No Action alternative because Bayer does not intend to globally launch FG72 soybean until the proper regulatory approvals have been obtained. To support commercial introduction of FG72 soybean in the U.S., Bayer intends to submit dossiers to request import approval of FG72 soybean to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean in place. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China.
Other Regulatory Approvals		
U.S.	Completed FDA consultation	Completed FDA consultation
Compliance with Other Laws		
CWA, CAA, Eos	Fully compliant	Fully compliant

4 ENVIRONMENTAL CONSEQUENCES

4.1 Scope and Assumptions of Analysis

4.1.1 Scope of this Analysis

This analysis of potential environmental consequences addresses the potential impact to the human environment from the alternatives analyzed in this EA. Potential environmental impacts from the No Action Alternative and the Preferred Alternative for FG72 soybean are described in detail throughout this section.

An environmental impact would be any change, positive or negative, from the existing (baseline) conditions of the affected environment (described for each resource area in Section 2). Impacts may be categorized as direct, indirect, or cumulative. A direct impact is an effect that results solely from a proposed action without intermediate steps or processes[18]. An indirect impact may be an effect that is related to but removed from a proposed action by an intermediate step or process[19].

A cumulative effects analysis is also included for each resource area in Section 5. A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. Examples include breeding FG72 soybean with other events no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act of 2000. If there are no direct or indirect impacts identified for a resource area, then there can be no cumulative impacts.

Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential impacts. Certain aspects of this product and its cultivation may be no different between the alternatives; those are described below.

4.1.2 Assumptions used in this Analysis

Geographic Boundaries of the Analysis

Although the Preferred Alternative would allow for new plantings of FG72 soybean to occur anywhere in the United States, APHIS will primarily focus the environmental analysis on those states that both support soybean production and permit the registered use of isoxaflutole on soybean[20], as these are the areas that are most likely to adopt FG72 soybean. These states are listed on the EPA-registered isoxaflutole label (Appendix A) and represented approximately 82 percent of U.S. soybean production in 2012 (Table 13).

Where appropriate, the environmental analysis will focus on regional impacts of the alternatives. The areas used for these analyses, where it occurs, are the same as those soybean production

[18] Examples include soil disturbance, air emissions, and water use.
[19] Examples include surface water quality changes resulting from soil erosion due to increased tillage or worker safety impacts resulting from an increase in herbicide use.
[20] These states also permit the registered use of isoxaflutole on field corn.

regions presented in Subsection 2.1.1 – Range and Acreage of Soybean Production (Midwest, Southeast, and Eastern Coastal regions). Soybean production was divided into 3 major regions in this EA based on geographical differences in the weed spectrum with a particular interest on glyphosate resistant weed populations. These soybean production regions were based principally on the regional chapters of the Weed Science Society of America (WSSA). These regions contain the major soybean production states (Table 13), with the exception of Minnesota, as well as all the states where isoxaflutole is registered for use on soybean (Figure 7). As stated in the previous paragraph, the states that support soybean production and permit the use of isoxaflutole represented approximately 82 percent of U.S. soybean production in 2012 (USDA-NASS, 2012c).

Table 13. Soybean production in states where isoxaflutole is registered for use on soybean

State	Planted Soybean Acreage	State	Planted Soybean Acreage	State	Planted Soybean Acreage
Alabama	340,000	Louisiana	1,130,000	North Dakota	4,750,000
Arkansas	3,200,000	Maryland	480,000	Ohio	4,600,000
Delaware	170,000	Michigan	2,000,000	Oklahoma	420,000
Florida	21,000	Minnesota	7,050,000	Pennsylvania	530,000
Georgia	220,000	Mississippi	1,970,000	South Carolina	380,000
Illinois	9,050,000	Missouri	5,400,000	South Dakota	4,750,000
Indiana	5,150,000	Nebraska	5,050,000	Tennessee	1,260,000
Iowa	9,350,000	New Jersey	95,000	Texas	125,000
Kansas	4,000,000	New York	315,000	Virginia	590,000
Kentucky	1,480,000	North Carolina	1,590,000	West Virginia	21,000
				Wisconsin	1,710,000

Soybean acreage is derived from USDA-NASS (2012c). Total U.S. soybean acreage in 2012 was approximately 77,000,000 acres. White cells represent states where isoxaflutole is not registered; yellow cells represent states where isoxaflutole is registered; green cells represent states where isoxaflutole is registered and where additional use restrictions are established beyond those on the EPA isoxaflutole label.

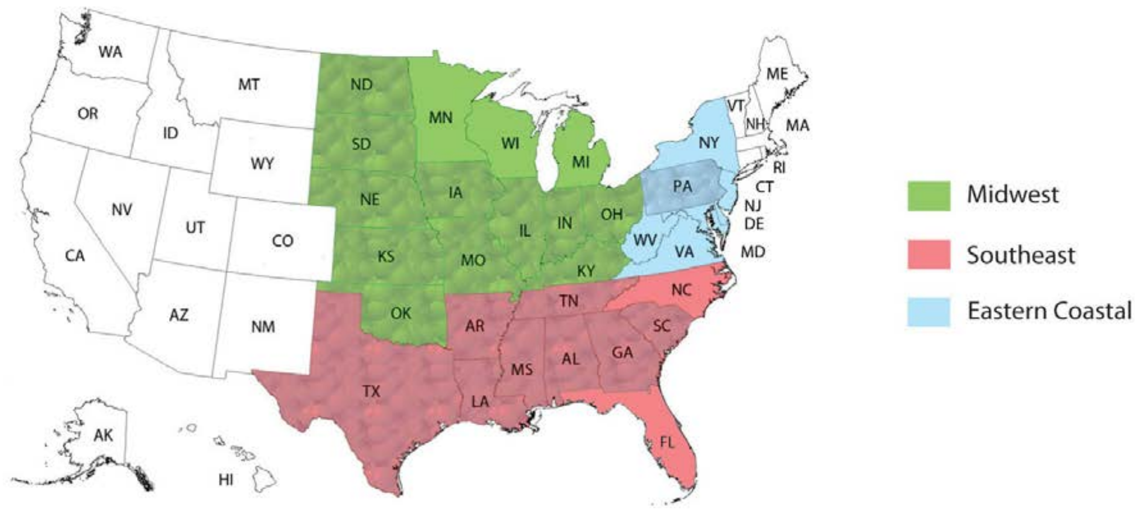


Figure 7. Soybean production regions and states where isoxaflutole is registered for use on soybean. Textured color pattern represents states within individual soybean production regions that support soybean production and where isoxaflutole is registered.

<u>Management Practices and Herbicide use in Soybean</u>

The environmental consequences of the different alternatives will be analyzed under the assumption that farmers, who produce conventional soybean, FG72 soybean, or produce soybean using organic methods, are using reasonable, commonly accepted best management practices (BMPs) for their chosen system and varieties during agricultural soybean production. Additionally, APHIS also assumes soybean growers that choose to cultivate FG72 soybean and apply isoxaflutole and glyphosate will use those (and any other) herbicides in accordance with federal and state registration labels, as legally obligated by the EPA:

> Once registered, a pesticide may not be legally used unless the use is consistent with the approved directions for use on the pesticide's label or labeling (EPA, 2013e).

EPA-approved isoxaflutole and glyphosate registration labels are presented in Appendix A.

FG72 soybean is designed to permit the use of a novel herbicide mode of action (MOA), HPPD-inhibition, on soybean through the use of isoxaflutole. Thus, under the Preferred Alternative, FG72 soybean may potentially impact soybean herbicide use practices, among other resource areas. Throughout the following analyses, APHIS will attempt to use the most recent soybean herbicide use data that is publically available. This generally includes, but is not limited to, data from USDA-NASS (2013e), USDA-ERS (2013a), and EPA (2013a). Other herbicide use data sources may also be used, including:

- Peer-reviewed literature;
- Reports published by state departments of agriculture and agricultural extension services;
- Personal communications with individuals representing federal, state, and agricultural extension services; and

- Previously-published material by APHIS[21].

All data and references cited in these analyses, as well as throughout this EA, are listed in Section 8 – References.

Herbicide-Resistant Weeds

As stated earlier in the previous subsection, APHIS assumes that FG72 soybean will only be cultivated in the 20 states listed on the EPA-registered isoxaflutole label[22]. APHIS also assumes that growers in those 20 states are adopting FG72 soybean with the intention of controlling problematic weeds, and in particular, glyphosate-resistant weeds, through the use of isoxaflutole application (Bayer, 2011c). The extent of glyphosate-resistant weed acreage in those 20 states, like the total acreage of glyphosate-resistant weeds in the entire United States, is not definitive due to the difficulty of glyphosate-resistant weed estimation (Carpenter and Gianessi, 2010).

The International Survey of Herbicide Resistant Weeds (ISHRW[23]) is an extensive and currently-maintained public database of herbicide-resistant weeds. The ISHRW database may be used to estimate the acreage of glyphosate-resistant weeds in the 20 states that cultivate soybean and where isoxaflutole is registered for use on soybean. APHIS consulted with Dr. Ian Heap, the curator of the database and the person most familiar with the limitations of the data within the database. This consultation resulted in an estimation of 10-20 million acres of glyphosate-resistant weeds in those states that cultivate soybean and where isoxaflutole is registered for use on soybean (personal communication with Ian Heap). Despite the limitations of this database (detailed in Appendix B), ISHRW remains the most comprehensive and extensive catalog of herbicide-resistant weed information that is publically available. The ISHRW database is often used by:

- Federal agencies (e.g., USDA-APHIS, 2012a);
- Academic faculty, agricultural extension agents, and members of the plant biotechnology industry (e.g., Nandula, 2010); and
- Non-government organizations (e.g., Center for Food Safety, 2012).

Consequently, APHIS will use this 10-20 million acre estimate to describe the extent of glyphosate-resistant weeds in those states that cultivate soybean and where isoxaflutole is registered for use on soybean.

APHIS also assumes that the application of isoxaflutole to FG72 soybean for the purposes of weed control will exert selection pressure for the development of isoxaflutole-resistant weed

[21] This includes previously-published APHIS NEPA documents (Environmental Assessments and Environmental Impact Statements), APHIS Plant Pest Risk Assessments, and petitions and supplements for a determination of nonregulated status previously published on the APHIS BRS website. All of these APHIS-published documents may be found at: http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml (Last accessed January, 2013).
[22] AL; AR; GA; IL; IN; IA; KS; KY; LA; MS; MO; NE; ND; OH; OK; PA; SC; SD; TN; and TX.
[23] The International Survey of Herbicide Resistant Weeds may be accessed at: http://www.weedscience.org/In.asp (Last accessed January, 2013). The database is the result of a collaborative effort by the Herbicide Resistance Action Committee, The North American Herbicide Resistance Action Committee, and the Weed Science Society of America

biotypes[24] in those fields. Where appropriate, APHIS assumes that isoxaflutole-resistance will develop in weed populations under intense selection pressure with isoxaflutole; accordingly, there is relevant field data showing this to be true with isoxaflutole (Hausman et al., 2011). In the relevant analyses, APHIS will focus on the capacity of the farmer to manage and control isoxaflutole-resistant weed populations, rather than absolute avoidance of isoxaflutole-mediated selection pressure for these weeds, because any weed management practice will exert selection pressure on weed populations (Nandula, 2010), including non-chemical selection pressure[25] (Barrett, 1983).

Isoxaflutole Risk Assessments

Any herbicide (or any other pesticide) in the United States must be registered by the EPA prior to any specific use in the United States. EPA regulates pesticide use under broad authority granted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (see 21 U.S.C. § 301 et seq.). EPA defines pesticide registration as:

> … a scientific, legal, and administrative procedure through which EPA examines the ingredients of the pesticide; the particular site or crop on which it is to be used; the amount, frequency, and timing of its use; and store and disposal practices. In evaluating a pesticide registration application, EPA assesses a wide variety of potential human health and environmental effects associated with the use of the product (EPA, 2013d).

EPA requires a variety of pre-defined tests in a pesticide registration package. The potential pesticide registrant must provide this data, according to EPA guidelines (EPA, 2013d). The data resulting from these tests is used by the EPA to produce an ecological risk assessment and human health risk assessment in order to:

> …evaluate whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish, and plants, including endangered species and non-target organisms, as well as possible contamination of surface water or ground water from leaching, runoff, and spray drift. Potential human risks range from short-term toxicity to long-term effects such as cancer and reproductive system disorders (EPA, 2013d).

Following submission of a complete pesticide registration package, EPA may decide to register or not register a pesticide. If EPA decides to register a pesticide, then the pesticide can only be used:

[24] The terms biotype and population will be used interchangeably throughout this EA.
[25] An example of a weed response to a non-chemical selection pressure is the development of barnyard grass that more closely resembles rice plants (in rice fields) after hand-weeding induced selection pressure (Barrett, 1983)

> …legally according to the directions on the labeling accompanying it at the time of sale. Following label instructions carefully and precisely is necessary to ensure safe use[26] (EPA, 2013d).

A successful pesticide registration by the EPA ensures that:

> …pesticides will be properly labeled and that, if used in accordance with specifications, they will not cause unreasonable harm to the environment (EPA, 2013b).

If the pesticide is to be used on a raw agricultural product intended for food or feed, then EPA must also grant a tolerance or exemption for that particular combination of pesticide and raw agricultural product. A tolerance is:

> …the maximum amount of a pesticide that can be on raw product and still be considered safe. Under the Food, Drug, and Cosmetic Act (FFDCA), a raw agricultural product is deemed unsafe if it contains a pesticide residue, unless the residue is within the limits of a tolerance established by EPA or is exempt from the requirement. The FDCA requires EPA to establish these residue tolerances (EPA, 2013b).

Before establishing a tolerance for a pesticide on a raw agricultural product for food or feed, EPA considers and addresses several factors, including:

- The aggregate, non-occupations exposure from the pesticide (exposure through diet, from using pesticides in and around the home, and from drinking water);
- The cumulative effects from exposure to different pesticides that produce similar effects in the human body;
- Whether there is increased susceptibility to infants and children, or other sensitive populations, from exposure to the pesticide; and
- Whether the pesticide produces and effect in humans similar to an effect produced by a naturally-occurring estrogen or produces other endocrine-disruption effects (EPA, 2011f).

Under the Food Quality Protection Act of 1996, which amended FIFRA and FFDCA, establishment of tolerance by EPA for a pesticide on a raw agricultural commodity intended for food or feed indicates that the pesticide:

> …poses a "reasonable certainty of no harm" before that pesticide can be registered for use on food or feed (EPA, 2011f).

In summary, a pesticide must be registered by the EPA prior to any legal use in the United States. During the pesticide registration process, EPA evaluates data related to the environmental and human health risks of the pesticide under authority granted by FIFRA. If the pesticide is intended to be used on a raw agricultural commodity intended for food and feed, EPA must also establish residue tolerances for that particular combination of pesticide and crop

[26] The language on a label may contain mitigation to limit environmental or human health risks.

under authority granted by the FFDCA. Pesticide label language must also be approved by the EPA. By registering a pesticide, EPA has effectively determined that there is "no unreasonable harm to the environment" and that the pesticide "poses a reasonable certainty of no harm" if it is used according to the label language (EPA, 2011f; EPA, 2013b; EPA, 2013d).

With regard to the registered-use of isoxaflutole on soybean that may be used for food or feed, APHIS assumes that EPA has carried out its responsibility under FIFRA and the FFDCA. EPA conducted and completed ecological and human health risk assessments for isoxaflutole use on soybean (EPA, 2010c; EPA, 2010d; EPA, 2011d). EPA also registered isoxaflutole as a restricted use pesticide (RUP) (Appendix A). Based on the EPA risk assessments for isoxaflutole and the EPA registration of isoxaflutole under FIFRA and the FFDCA, APHIS assumes that use of isoxaflutole will cause "no unreasonable harm to the environment" and its inclusion in food and feed "poses a reasonable certainty of no harm," when used according to the language on the isoxaflutole label.

A description of isoxaflutole and a summary of the EPA risk assessments for isoxaflutole are presented in Appendix C and will be cited throughout the environmental analyses in this section.

4.2 Agricultural Production of Soybean

4.2.1 Range and Acreage of Soybean Production

<u>No Action Alternative: Range and Acreage of Soybean Production</u>

In 2012, approximately 77.2 million acres of soybeans were planted in the United States (USDA-NASS, 2012b). Soybeans were commercially cultivated in 31 states, with Iowa (9,350,000 planted acres); Illinois (9,050,000 planted acres); and Minnesota (7,050,000 planted acres) representing the top three U.S. soybean production states (USDA-NASS, 2012b).

Under the No Action Alternative, the range of U.S. soybean production is unlikely to expand beyond those states where soybean is already cultivated, as the number of U.S. states that commercially cultivated soybean has remained constant for the past decade (USDA-NASS, 2013g).

Like any other agricultural crop, the number of soybean acres planted in any given year is ultimately dependent on the market for soybean products (USDA-ERS, 2013d). Under the No Action Alternative, existing trends related to the cultivation and proportion of crop acreage planted with soybean in the U.S. are expected to continue. U.S. planted soybean acreage is anticipated to gradually decrease to approximately 76 million acres in 2022 from 77.2 million acres in 2012 (Figure 8). While representing a decrease of one-million acres, this slight decrease in soybean acreage is reflective of relatively stable levels of U.S. soybean acreage. In general, between 73 and 77 million acres of soybean was planted in the United States during the past decade (USDA-NASS, 2013f). While the 65 million acres of soybean planted in 2007 would typically represent the lower limit of this range (USDA-NASS, 2013f), 2007 was a bit of an outlier[27], due to the extremely strong demand for ethanol that encouraged many U.S. growers to plant corn at the expense of soybean (USDA-ERS, 2011e). However, even when considering 2007, the resilience of the soybean market is readily apparent in the next and subsequent years, when U.S. soybean acreage quickly rebounded to more typical levels (Figure 8).

It is important to note that U.S. farms will vary the source of soybean acreage from year to year (USDA-ERS, 2010d; USDA-ERS, 2011c; USDA-ERS, 2013d). This represents a dynamic process, where farm-level decisions result in the shifting of land from one crop to another. In general, soybean is profitably grown on high quality agricultural land, not lands of lower productivity (EIA, 2007; USDA-NASS, 2011b). Much of the high quality land in the United States is already committed to agricultural production (EPA, 2007) and in 2002, USDA-ERS estimated that only 2.1 percent of cropland was idle (Lubowski et al., 2002). At the same time, total U.S. agricultural acreage decreased (EIA, 2007). To satisfy greater soybean demand during the years of increased soybean acreage, additional soybean acreage was generally planted at the expense of alternative crops (such as corn, as seen in Figure 8), with minor contributions from land exiting Conservation Reserve Program (CRP) agreements (O'Brian, 2010; USDA-ERS, 2011e). Due to this pattern of land-crop shifting, it is unlikely that previously uncultivated land will be managed for future soybean production, but rather that growth of soybean production will compete with other agricultural plantings (EIA, 2007; USDA-ERS, 2011d).

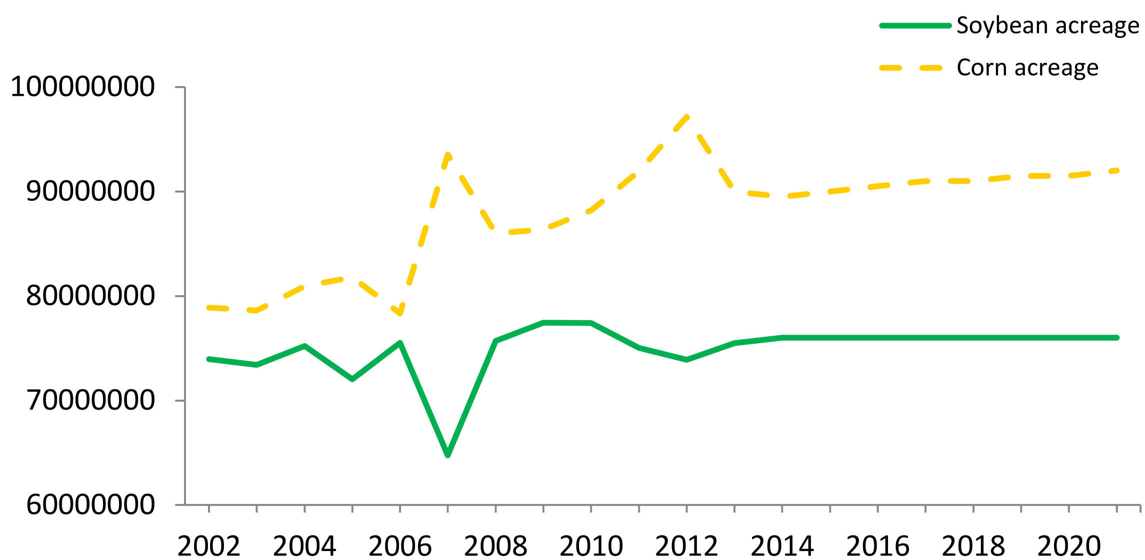


Figure 8. **U.S. soybean and corn acreage, 2002 – 2022.**
Data spanning 2002 – 2012 was derived from the USDA-NASS Quick Stats online database (2013f). Projection data from 2013 – 2021 was derived from USDA-ERS(USDA-ERS, 2013d).

In summary, the continued domestic and international demand for U.S. soybean products, coupled with relatively high soybean commodity prices, is likely to continue increasing (USDA-ERS, 2012b; USDA-ERS, 2013d) under the No Action Alternative. In response, based on soybean production trends and projections, soybeans will continue to be a major crop in the U.S.

[27] "An outlier is an observation that lies outside the overall pattern of a distribution. Usually, the presence of an outlier indicates some unexpected deviation from the normal variation." Source: http://mathworld.wolfram.com/Outlier.html

for the foreseeable future (USDA-ERS, 2013d). In order to accommodate this continued need for U.S. soybean acreage in spite of a net decrease in available U.S. agricultural land (EIA, 2007), growers are likely to plant additional soybean acreage at the expense of other crops, such as corn, cotton, or hay (O'Brian, 2010; USDA-ERS, 2011e). The use of existing agricultural land in lieu of previously uncultivated land for additional soybean acreage is a necessary land-use decision, as soybean is profitably grown on high quality arable land, not land of lower productivity (EIA, 2007; USDA-ERS, 2011d).

Preferred Alternative: Range and Acreage of Soybean Production

Under the Preferred Alternative, a determination of a nonregulated status of FG72 soybean is unlikely to expand soybean acreage as described in the No Action Alternative for two major reasons. First, FG72 soybean is unlikely to disrupt the causal relationship between market forces and U.S. soybean acreage, which is ultimately affected by growing domestic and international demand for soybean commodity products, such as animal feed or industrial oils/plastics (USDA-ERS, 2012b; USDA-ERS, 2013d). Secondly, FG72 soybean is unlikely to expand soybean acreage beyond projected values (USDA-ERS, 2013d) because it requires similar management conditions as conventional soybean, does not present any absolute yield gains over conventional soybean varieties under typical management conditions, and exhibits no phenotype that would be indicative of an improved capacity to grow outside an agricultural environment (Bayer, 2011c; USDA-APHIS, 2012d). Similar to currently available soybean varieties, FG72 soybean will likely require cultivation on high quality arable land to produce a grower profit, precluding the use of lower quality, uncultivated land to supply additional soybean acreage. FG72 soybean is unlikely to be cultivated on land not previously used for agriculture, thus maintaining observed farm-level land-use decisions to shift agricultural land away from other crops, such as corn, cotton, or hay, toward soybean production to satisfy market demand (USDA-ERS, 2010d; USDA-ERS, 2011c; USDA-ERS, 2013d).

4.2.2 Agronomic Practices

No Action Alternative: Tillage

The current trend of increasing conservation tillage adoption is unlikely to change under the No Action Alternative, due to the extensive market penetration of glyphosate-resistant soybean varieties (Dill, 2005; Owen, 2010) and its relationship with conservation tillage practices (Givens et al., 2009; USDA-ERS, 2010a; Bonny, 2011). The adoption of conservation tillage practices by U.S. soybean growers increased from 51 percent of planted acres in 1996 to 63 percent in 2008, or an addition of 12 million acres. The adoption of no-till practices accounted for most of the increase and was used on 85 percent of these additional 12 million acres. (CTIC, 2008; NRC, 2010a). In 2011, over 65% of U.S. soybean acres used some form of conservation tillage (USB, 2011b). Conservation tillage adoption rates by U.S. soybean growers are likely to be sustained by the continued use of glyphosate as a broad-spectrum herbicide(Carpenter and Gianessi, 1999) that enables conservation tillage strategies to be undertaken as an economical alternative to conventional tillage (Givens et al., 2009; USDA-ERS, 2010a).

In the presence of glyphosate-resistant weeds, some U.S. soybean growers may reincorporate the use of conventional tillage practices to manage those problematic weed populations (NRC, 2010a). However, in spite of increasing concern with glyphosate-resistant weed populations, the majority of U.S. growers are likely to continue using glyphosate in their weed management strategies. This is due to several reasons, though the most relevant include the substantial costs of conventional tillage (USDA-NRCS, 2011), grower familiarity with glyphosate (Johnson et al., 2009; NRC, 2010a; Owen et al., 2011c), and the overall value placed on simplicity and convenience that is provided by glyphosate-resistant systems (Owen, 2010). These reasons, coupled with the extent of glyphosate-resistant weeds in U.S. soybean fields (at least 3 percent of U.S. soybean acreage) (Owen, 2010), suggest that the use of conservation tillage is likely to continue as practiced.

In response to the emergence of glyphosate-resistant weeds, growers have been encouraged to incorporate diverse weed management practices, including tillage, along with the use of herbicides, as the guiding principle for managing resistance and shifts in weed population (Owen et al., 2011c; Norsworthy et al., 2012; Vencill et al., 2012). Several researchers report that as a result of the emergence of herbicide-resistant weed strains, growers have returned to conventional tillage systems to control these weeds. For example, growers managing glyphosate-resistant Palmer amaranth (*Amaranthus palmeri*) and Horseweed (or marestail, *Conyza canadensis*) have been reported to revert to conventional tillage systems in order to obtain effective control (Steckel and Montgomery, 2008; Price et al., 2011).

Growers must carefully balance all of the management strategies available in managing these hard to control weeds, including balancing the benefits of conservation tillage with the need to control these herbicide resistant weeds using mechanical methods (Norsworthy et al., 2012; Shaw et al., 2012).

<u>Preferred Alternative: Tillage</u>

Effective broad-spectrum herbicide use is generally associated with the adoption of conservation tillage in U.S. soybean production practices (NRC, 2010a). Similar to the No Action Alternative, FG72 soybean permits the continued use of an existing broad-spectrum herbicide (glyphosate) that contributed to the general use of conservation tillage in U.S. production fields; additionally, FG72 soybean will permit the use of another broad-spectrum herbicide, isoxaflutole. The presence of the glyphosate-resistant phenotype in FG72 soybean will permit the continued use of glyphosate as it is used presently in conventional U.S. soybean production, maintaining current trends of conservation tillage (Owen, 2010; Bonny, 2011); (Owen et al., 2011c). Concurrently, FG72 soybean will also permit the use of isoxaflutole, another effective broad-spectrum herbicide that will permit the continued use of conservation tillage in U.S. soybean production fields (Bayer, 2011a; Bayer, 2011b). Growers cultivating FG72 soybean will be able to continue to rely on herbicides and avoid reversion to conventional tillage as a weed control alternative when confronted with glyphosate-resistant weeds. Thus, there is no reason to suspect that a determination of nonregulated status of FG72 soybean would alter the shift toward conservation tillage in soybean, as FG72 soybean will represent another herbicide-resistant soybean variety that may facilitate the use of conservation tillage (AOSCA, 2011).

<u>No Action Alternative: Crop Rotation</u>

According to USDA-ERS, 95 percent of the U.S. soybean-planted acreage has been in some form of a crop rotation system since 1991 (USDA-ERS, 2011b).

The decision to rotate alternative crops following soybean cultivation include economic and management considerations. For example, a farmer may choose to plant a crop that provides a higher financial return than soybean the following season, as occurred during the corn-ethanol boom in 2007 when corn acreage increased primarily at the expense of soybean acreage (see Subsection 4.2.1 Range and Acreage of Soybean Production and USDA-ERS, 2011e). However, economic considerations are only one consideration a farmer takes into account when planning for the following growing season. Management considerations are also considered. Crop rotation may produce agronomic benefits on an agricultural field, including (Al-Kaisi et al., 2003):

- Improved crop yield;
- Decreased need for additional nitrogen the following growing season;
- Mitigation of microbial, insect, and weed pest cycles;
- Reduced soil erosion and improved soil quality; and
- Reduced agricultural runoff.

Crop rotation is strongly encouraged as an element of weed management strategies (see, e.g., (HRAC, 2012). HRAC recommends that growers adopt full rotation, involving not only rotating crops (e.g. soybean following corn) but also rotating herbicide-resistance variety (e.g. glyphosate-resistant corn followed by glufosinate-resistant soybean) (HRAC, 2012). Such a rotation strategy is recommended as part of a grower strategy to delay the risk of development of herbicide resistant weeds. These crop rotation considerations are not expected to change under the no action alternative.

A farmer may choose a variety of crops to rotate with soybean. While often dependent on farmer want and need, choice of rotation crop may also be partially reflective of the region where a particular soybean crop is cultivated. In the Midwest and Eastern Coastal soybean production regions, corn is the primary crop rotated with soybean; however, in the Southeast region, cotton is an important rotation with soybean (Table 14). Additionally, a wider variety of crops is rotated with soybean in the Midwest compared to the other soybean production regions; dry peas, flax, millet, and sugar beet are rotated with soybean in the Midwest and not the other production regions (Table 14). Growers applying herbicides need to consider herbicide residue and soil carryover as a possible constraint on crop rotation practices. Herbicides will provide restrictions and limitations intended to avoid rotational crop damage.

Table 14. Soybean rotation crops in U.S. soybean production regions 2008

	Regions		
Crop	**Midwest**	**Southeast**	**Eastern Coastal**
Alfalfa	1,617		
Barley	1,929		
Corn	77,260	3,535	3,615
Cotton	341	2,380	61
Dry Beans	1,166		
Dry Peas	520		

	Regions		
Crop	**Midwest**	**Southeast**	**Eastern Coastal**
Flax	345		
Millet	250		
Oats	1,590		
Potatoes	278		
Rice	200	1,631	
Sorghum	3,553	245	
Soybeans	62,150	10,430	1,705
Sugar Beets	830		
Wheat	32,039	1,530	
Other Vegetables	342	65	45
Total	184,410	19,816	5,426

All acreage is expressed as 1000s of acres.
Source: USDA-NASS (2013c) and Table VIII-25-27 in Monsanto (2012)

Under the No Action Alternative, rotation strategies for soybean will continue as practiced today, with market demand and available technology strongly influencing these practices. These trends are not specific to a single GE soybean variety and are expected to continue as normally practiced under the No Action Alternative.

Preferred Alternative: Crop Rotation

Similar to the No Action Alternative, a determination of nonregulated status of FG72 soybean is unlikely to substantially change current patterns of soybean crop rotation because it exhibits similar agronomic performance relative to its nontransgenic parent variety, Jack (Bayer, 2011c). In particular, no differences in phytopathology were generally observed between FG72 and its nontransgenic parent variety (Jack) in experimental plots (USDA-APHIS, 2012d). These similar measures of disease susceptibility suggest that FG72 soybean would benefit from currently-practiced soybean rotation strategies. Furthermore, cultivation of FG72 soybean and potential corresponding isoxaflutole use may not restrict common corn/soybean rotation, as the rotation interval for corn following isoxaflutole use is 0 months (Bayer, 2011b).

As discussed in No Action: Crop Rotation, growers currently adopt crop rotation strategies based upon market and field conditions. Approving the petition for nonregulated status for FG72 soybean is unlikely to change these market conditions, as market demand for soybean is dependent on product end use and not any one GE soybean variety. Accordingly, crop rotation in soybean is unlikely to be substantially different under the Preferred Alternative compared to the No Action Alterative.

No Action Alternative: Fertilization

Compared to other crop plants, soybean cultivation requires less nitrogen fertilization. USDA-ERS estimates that less than 40 percent of soybean acres in the U.S. receive nitrogen fertilizer (USDA-ERS, 2010c); this trend of percent soybean acreage treated with nitrogen fertilizer, along with application rates of nitrogen fertilizer, have remained relatively constant since 1992. Under the No Action Alternative, current trends related to fertilizer use in U.S. soybean production are not anticipated to substantially change.

Preferred Alternative: Fertilization

Similar to the No Action Alternative, a determination of nonregulated status of FG72 soybean is unlikely to substantially change fertilization patterns in U.S. soybean production. Standard agricultural practices are required for the cultivation of FG72 soybean, demonstrating that it requires typical quantities of nitrogen in the soil (Bayer, 2011c). In general, GE herbicide resistant soybean varieties have not required more supplemental nitrogen fertilization compared to other soybean varieties, despite the increase in GE soybean variety adoption (Figure 9). Current trends related to fertilizer use in U.S. soybean production are not anticipated to change under the preferred alternative.

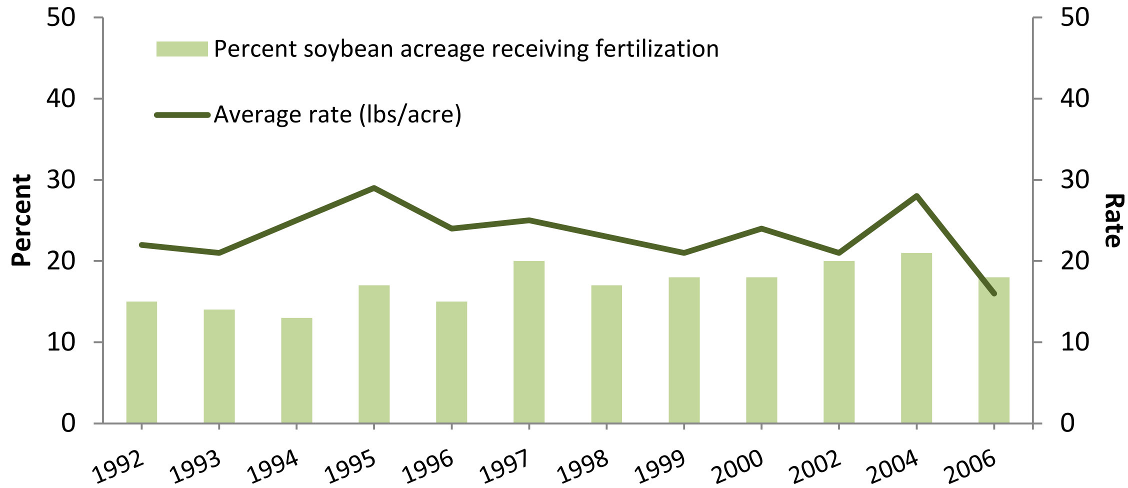


Figure 9. Percent and application rate of nitrogen fertilization in U.S. soybean production, 1992 – 2006. Source: USDA-ERS (2011g; 2011f).

No Action Alternative: Pest Management

Under the No Action Alternative, pesticide use in U.S. soybean fields will likely continue as it is currently practiced. While insecticide use in U.S. soybean production is an important management practice to protect soybean yield, insecticide application in soybean will likely continue to be restricted to a small percentage of soybean acres (USDA-NASS, 2002a; USDA-NASS, 2007a), due in large part to the capacity of soybean to experience limited insect herbivory without a reciprocal loss in grain yield (Penn State Extension, 2011). Management practices and trends related to fungicide application described in Subsection 2.1.2 – Agronomic Practices are likely to continue as practiced today. The application of fungicides for seed treatment is expected to continue to increase as more fungicide treatments are brought to the market (see e.g., (Hoeft et al., 2000; Ruhl, 2012). Grower decisions on fungicide and insecticide applications are not expected to change under the No Action Alternative.

With regard to weed management practices, U.S. soybean growers will continue to have access to herbicide-resistant soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. U.S. soybean growers will likely continue utilizing herbicides, primarily in the form of glyphosate, as the basis of a weed management system due to the extensive adoption of glyphosate-resistant soybean varieties (Carpenter and Gianessi, 1999; Fernandez-Cornejo and McBride, 2000) and grower preference for the familiarity and convenience of glyphosate-resistant soybean systems (USDA-ERS, 2011a). Since the introduction of glyphosate-resistant soybean varieties, glyphosate application has increased at the expense of alternative herbicides, with respect to total pounds of active ingredient applied (Fernandez-Cornejo et al., 2009). This statement, however, should not be misinterpreted to mean that the diversity of herbicides available to U.S. soybean growers has decreased; rather, the diversity of herbicides used in U.S. soybean production fields has gradually increased while applied quantities of those same herbicides (except glyphosate) have generally decreased (USDA-NASS, 1996; USDA-NASS, 2002b; USDA-NASS, 2007b; NRC, 2010b).

The interpretation of the long-term trends related to herbicide use resulting from the utilization of GE technologies are the subject of much debate (Benbrook, 2009; Fernandez-Cornejo et al., 2009; Brookes and Barfoot, 2010; Benbrook, 2012; Brookes and Barfoot, 2012b; Brookes et al., 2012). Benbrook reported that the adoption of herbicide-resistant crops has resulted in an increase in the volume of herbicides applied to crops (see e.g., (Benbrook, 2009; Benbrook, 2012). Benbrook noted that between 1996 and 2001, herbicide use declined apparently in direct response to the adoption of herbicide-resistant crops. However, since 2001, herbicide use has increased (Benbrook, 2009; Benbrook, 2012). Benbrook suggests that the reported increases in herbicide use during the last decade reflect an increase in glyphosate applications as more glyphosate-resistant crops are planted with an associated increase in use of other herbicides used to control glyphosate-resistant weeds (Benbrook, 2009; Benbrook, 2012). Other authors interpret the herbicide use data differently (see (Brookes and Barfoot, 2012b; Brookes et al., 2012). Benbrook's analysis of trends in herbicide use is based on assumptions that may lead to overestimates of herbicide use in herbicide-resistant crop programs, including assumptions of herbicide usage on conventional crops that may be underestimated, extrapolation of trends to years where no USDA data are available, and not accounting for the role of increased crop acreage in the estimated increases in herbicide use (Brookes et al., 2012). Further, Benbrook’s analysis fails to consider the differing environmental profiles of herbicides used, particularly the substitution of relatively environmentally benign products for those with less environmentally friendly profiles[28] (Brookes et al., 2012). In contrast to Benbrook's findings, Brookes and Barfoot(Brookes and Barfoot, 2012a) estimate that the volume of herbicides used in GE soybean crops decreased by 34 million kg between 1996 and 2010. The overall environmental impact associated with herbicide use on these crops also decreased, highlighting the switch in herbicides used with most GE herbicide resistant crops to active ingredients with a more environmentally benign profile than the ones generally used on conventional crops (Brookes and Barfoot, 2012a).

As discussed in Subsection 2.1.2 – Agronomic Practices, it is undisputed that the wide adoption of glyphosate-resistant soybean varieties has resulted in dramatic changes in glyphosate applications, from 20% of U.S. soybean acres in 1995, to over 98% of U.S. soybean acres in the 19 program states in 2006 (Figure 10) (USDA-NASS, 2007a). Because of the broad spectrum herbicide activity of glyphosate, many growers only applied glyphosate for their total weed management and reduced their reliance on diversified weed management practices (see e.g. (Owen et al., 2011a; Norsworthy et al., 2012; Vencill et al., 2012). As a result of these practices, there has been an increase in the number of crop acres with glyphosate-resistant weed populations over the last decade (Owen, 2008; Duke and Powles, 2009).

[28] To illustrate one of the challenges with Benbrook's presentation, one can compare basic pesticide environmental safety profiles using standard pesticide product labels. The EPA-approved pesticide labels, including herbicide labels, provide specific label statements and directions to the user so as to minimize human health and environmental impacts EPA, Basic Principles of the Worker Protection Standard, 2012a, EPA, Available: http://www.epa.gov/oppfead1/safety/workers/principl.htm.. For example, for human health, these label statements will include "signal words", which convey to the applicator the overall acute toxicity hazard posed by the product NPIC, Signal Words: Topic Fact Sheet, 2008, National Pesticide Information Center, Available: http://npic.orst.edu/factsheets/signalwords.pdf., as well as Restricted Entry Intervals (REI), during which time workers are excluded from entering a pesticide treated area EPA, Basic Principles of the Worker Protection Standard.. Three signal words are used: Caution, Warning, and Danger, with caution presenting the lowest acute toxicity hazard, and danger presenting the highest toxicity hazard NPIC, Signal Words: Topic Fact Sheet.. Using these label statements and direction, glyphosate is identified as low toxicity or very low toxicity and carries a "caution" label and a REI of 4 hours Monsanto, Roundup Power Max Herbicide Specimen Label, 2010, Monsanto Company, Available: http://www.cdms.net/LDat/ld8CC045.pdf, November 22 2011.; acifluorfen, one of the herbicides listed on Table 5, carries a "Danger" signal word, and has a 48-day reentry interval RedEagle, Acifluorfen 2 Label, 2012, Available: http://www.agrian.com/pdfs/RedEagle_Acifluorfen_2_Label.pdf..

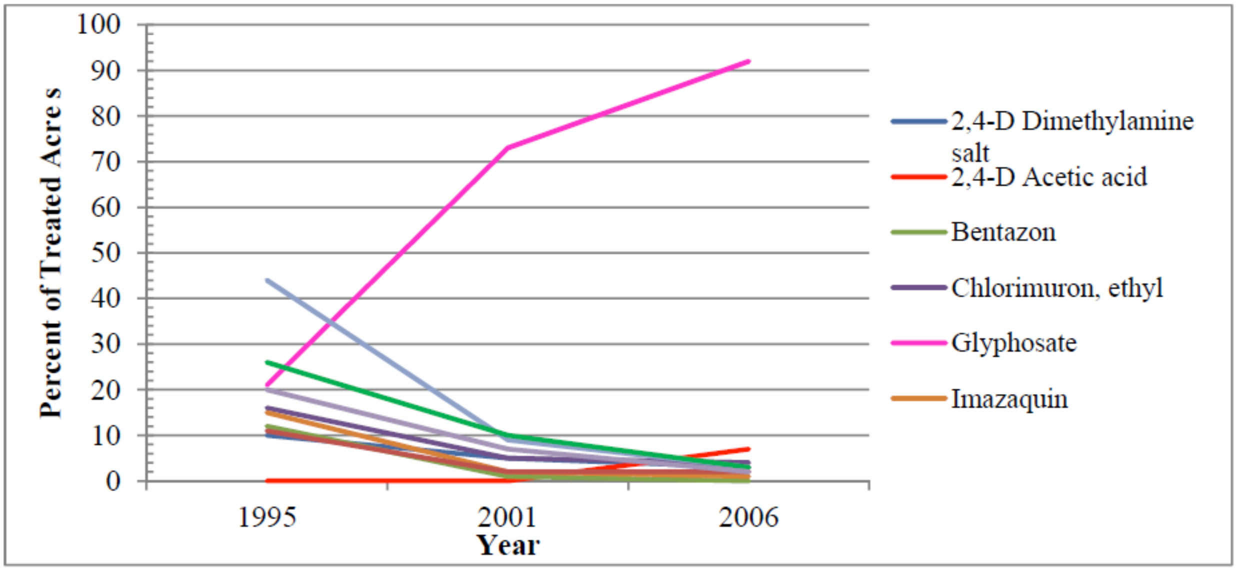


Figure 10. U.S. Soybean herbicide use trends: percent of U.S. soybean acres treated with the most commonly applied herbicides: 1995, 2001 and 2006 in select survey states[1]. Source: (USDA-NASS, 2007a).

Notes:

1. Survey states are as follows:
2. 1995: Arkansas, Georgia, Illinois, Indiana, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, Ohio, and Tennessee.
3. 2001: Arkansas, Illinois, Indiana, Iowa, Minnesota, Missouri, Nebraska, and Ohio.
4. 2006: Arkansas, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, and Wisconsin.

With any herbicide use, the potential exists for the selection of weeds resistant to that herbicide (Vencill et al., 2012). Within a weed species, individuals may possess an inherent ability to resist the effects of a particular herbicide; repeated use of that herbicide will expose the weed population to a "selection pressure," which may lead to an increase in the number of surviving resistant individuals in the population (Owen et al., 2011a; Vencill et al., 2012). Additionally, the application of herbicides at rates below those indicated on the EPA-approved label for the weed species and sole reliance on a single herbicide for weed control without the use of other herbicides or cultural control methods (i.e., pre-plant and in-crop tillage) may result in weed shifts and selection for weeds resistant to that single herbicide (Beckie, 2006; Peterson et al., 2007). In other words, plants susceptible to the applied herbicide will die; whereas, those few having some type of natural resistance will survive and reproduce (Vencill et al., 2012).

Weed resistance is generally defined by the Weed Science Society of America (website at www.wssa.net) as: (1) the ability to survive application rates of an herbicide product that once were effective in controlling it; and (2) resistance is heritable. Herbicide-resistant weeds are neither a new phenomenon nor unique to the use of glyphosate. Growers have been managing herbicide-resistant weeds for decades with the use of alternative herbicides and/or cultural methods such as tillage or crop rotation. Weed resistance to herbicides is a concern in agricultural production and the wide-spread adoption of herbicide-resistant crops, especially GE-derived glyphosate-resistant crops, has dramatically changed the approach that farmers take to avoid yield losses from weeds (Gianessi, 2008; Duke and Powles, 2009; Norsworthy et al., 2012). Subsections 2.3 and 4.4 – Biological Resources, discuss herbicide-resistant weeds in the context of soybean weed management.

The occurrence of an herbicide-resistant weed biotype generally does not end the useful lifespan or preclude the effective use of the herbicide in question as part of an overall weed management system (Owen et al., 2011a; Vencill et al., 2012). This is particularly true for glyphosate due to the wide spectrum of weeds it effectively controls and its ability to control a weed at different growth stages, despite its lack of effectiveness on some specific resistant weed biotypes (Owen et al., 2011a). The increasing frequency of glyphosate-resistant weeds in some soybean production fields may decrease the technical efficacy of glyphosate in controlling weeds. In spite of this, some U.S. soybean growers are hesitant to stop using glyphosate due to familiarity and comfort with the glyphosate-resistant soybean system. For example, a survey of 400 corn, cotton, and soybean growers found that a majority would not restrict their use of glyphosate-resistant crops [or glyphosate] when facing increased weed pressure from glyphosate-resistant weed populations (Scott and VanGessel, 2007). Similarly, Delaware soybean growers continued planting and cultivating glyphosate-resistant soybean varieties in the presence of glyphosate-resistant horseweed (Scott and VanGessel, 2007).

In response to the emergence of glyphosate-resistant weeds, growers have been encouraged to incorporate diverse weed management practices along with the use of glyphosate as the guiding principle for managing resistance and shifts in weed population (Owen et al., 2011a; Norsworthy et al., 2012; Vencill et al., 2012). A variety of strategies have been proposed to help farmers deal with glyphosate-resistant weeds (Beckie, 2006; Frisvold et al., 2009; Norsworthy et al., 2012), including:

- The rotation of herbicides with different MOAs;
- Site specific herbicide applications;
- Use of full labeled application rates;
- Crop rotation;
- Use of tillage for supplemental weed control;
- Cleaning equipment between fields;
- Controlling weed escapes;
- Controlling weeds early; and
- Scouting for weeds before and after herbicide applications.

Weed control methods differ depending on a number of factors including regional practices, grower resources, and crop trait; the techniques may be direct (e.g., mechanical, biological, and chemical) or indirect (e.g., cultural) (Ferrell et al., 2012; Loux et al., 2012). Additionally, weed management strategies need to be carefully planned to integrate appropriate technologies into an economic level of control (Carpenter and Gianessi, 2010). A diverse strategy is essential to reduce selection pressure on the weed population (Powles and Preston, 2009). Growers are recommended to adjust and adapt their weed management strategies, and to specifically include the use of herbicides with alternative MOAs, including auxin growth regulators, amino acid inhibitors, chlorophyll pigment inhibitors, or lipid biosynthesis inhibitors (Ross and Childs, 2011; Norsworthy et al., 2012).

The practice of using herbicides with alternative modes of action could potentially diminish the populations of glyphosate-resistant weeds and reduce the likelihood of the development of new herbicide-resistant weed populations (Dill et al., 2008; Duke and Powles, 2008; Owen, 2008; Duke and Powles, 2009; Norsworthy et al., 2012; Vencill et al., 2012). The evolution of herbicide-resistant weed populations is a natural response to selection pressure, in this case, the application of herbicide chemicals (Norsworthy et al., 2012). Repeated application of herbicides with the same MOA is the single-greatest risk factor for herbicide-resistance selection, favoring the survival and reproduction of weeds resistant to that herbicide (Beckie, 2006; Norsworthy et al., 2012). Using different herbicide MOAs in annual rotations, tank mixtures, and sequential applications can delay the evolution of herbicide-resistant weeds by minimizing the selection pressure imposed on those weed populations by a single herbicide (Norsworthy et al., 2012).

Weed-resistance management programs that integrate the use of herbicides with different MOAs and short soil residual activity reduces directional selection to a single herbicide (Prather et al., 2000), particularly when used in conjunction with crop rotation, which may allow the grower to manipulate planting times to avoid early-season weed germination (Jordan et al., 1995). In an annual herbicide rotation, crops in two or more subsequent cropping seasons receive different herbicide MOAs (HRAC, 2013). Mixtures and sequential applications can be used as a resistance management technique by applying different herbicides to the same crop during the same growing season, simultaneously, in the case of a mixture, and at different times for an herbicide sequence (HRAC, 2013).

Herbicide manufactures incorporate EPA's guidelines for pesticide resistance management into the herbicide labels. For example, EPA-approved labels for Roundup® branded herbicide weed-resistant management recommendations are designed to minimize the potential for the development of glyphosate-resistant weeds. (An example of current Roundup PowerMAX® product label is available at http://www.cdms.net/LDat/ld8CC045.pdf).

Soybean growers have the option to select alternative herbicide-resistant soybean varieties as a management tool to confront glyphosate-resistant weeds, including cultivation of the LibertyLink® varieties, which are resistant to glufosinate (Zenk, 2012). Additional varieties of herbicide-resistant soybeans may be available in the future. In addition to selecting alternative herbicide-resistant soybean varieties, growers are already introducing herbicides with different MOAs as part of their weed control strategy in glyphosate-resistant cropping systems. In a 2005 grower survey, 15 to 21% of growers applied non-glyphosate herbicides in addition to glyphosate for weed control in glyphosate-resistant soybean (Givens et al., 2009).

These non-glyphosate herbicides were applied prior to planting, at planting, and/or post-emergence in soybean (Givens et al., 2009). Prince et al., (2011) reported that between 46% and 54% of surveyed Roundup Ready® growers (corn, cotton and soybeans) who responded that they did not have glyphosate-resistant weeds on their farm used either a non-glyphosate residual and/or post-emergence herbicide in the 2009 growing season (Prince et al., 2011). For growers indicating they have on-farm herbicide-resistant weed populations to other herbicides, the percentage of growers was higher at 72% to 75%. This same survey reports that 45% of surveyed growers with on-farm glyphosate-resistant weeds rotated between glyphosate-resistant and non-glyphosate-resistant crops, and 50% of these growers rotated chemistries on a yearly basis (Prince et al., 2011). Surveys of international growers have identified similar trends. By 2003, 70% of Saskatchewan to 90% of Manitoba farmers claimed to rotate herbicides; in Australia, by 1998 the adoption rate of herbicide group rotation was 85% (Powles et al., 1996; Diggle et al., 2003; Beckie, 2006; Beckie and Reboud, 2009). These practices are consistent with current recommendations to use herbicides with different MOAs in a grower's weed management program to reduce the likelihood of establishment of herbicide-resistant weed populations in grower's fields (Duke and Powles, 2009; Norsworthy et al., 2012; Vencill et al., 2012).

U.S. soybean growers, are beginning to understand that a diversification of selection pressure in their weed management strategies may be necessary to manage and slow glyphosate-resistant weed development (Johnson et al., 2009; NRC, 2010b; Owen et al., 2011c). One general farm-level response to glyphosate-resistant weeds has been to increase the rate/frequency of glyphosate application and incorporate the use of different herbicidal chemistries (NRC, 2010b). A possible consequence of this action may be an absolute increase in total herbicide use (lbs. ai/acre) in U.S. soybean production (NRC, 2010b; Owen, 2010). It is prudent to mention, however, that total herbicide use may not be an effective metric to measure environmental impact, as this does not effectively permit the environmental comparison of different herbicides across time or across management strategies (Fernandez-Cornejo et al., 2009).

As discussed in Subsection 2.1.2 – Agronomic Practices, and noted above, the most effective weed management practices integrate a diverse combination of mechanical, cultural, and/or herbicide control strategies (Owen et al., 2011a; Loux et al., 2012; Norsworthy et al., 2012). A diverse strategy is essential to reduce selection pressure on the weed population and thus limit the potential development of herbicide-resistance in other weed species (Powles and Preston, 2009; HRAC, 2013). Table 15 presents these agronomic management strategies and shows the comparative risk of herbicide-resistance associated with the adoption of these various strategies.

Table 15. Comparative risk of resistance associated with weed management strategies.

Management Strategy	Risk of Resistance		
	Low	**Moderate**	**High**
Herbicide mix or rotation in cropping system	>2 MOA[1]	2 MOA[1]	1 MOA[1]
Weed control in cropping system	Cultural[2], mechanical[3] and chemical	Cultural[2] and chemical	Chemical only
Use of same MOA[1] per season	Once	More than once	Many times
Cropping system	Full rotation[4]	Limited rotation[4]	No rotation
Resistance status to MOA[1]	Unknown	Limited	Common
Control in last three years	Good	Declining	Poor

Source:(HRAC, 2013).

Notes:

1 MOA – Mode of Action as defined by the Herbicide Resistance Action Committee

2 Cultural controls include clean seed, soybean variety, seeding rate and row spacing, crop rotation, planting date, competitive crops, stale seedbeds, etc.

3 Mechanical controls include a range of tillage practices.

4 Full rotation involves not only rotating crops (e.g. soybean following corn) but also rotating herbicide-resistance variety (e.g. glyphosate-resistant corn followed by glufosinate-resistant soybean). Limited rotation would include strategies where corn and soybean may be part of a crop rotation plan, but both crops are glyphosate-resistant.

Under the No Action Alternative, growers likely will continue to experience the continued emergence of glyphosate-resistant weeds. The strategies identified in the above table, including grower's application of multiple herbicides with different MOAs, variable weed control strategies (including cultural and mechanical controls), and both herbicide and crop rotations as part of the growers' management strategy to decrease the risk of herbicide-resistant weeds, continue under the No Action Alternative (Norsworthy et al., 2012).

Because glyphosate does not provide residual weed control, growers are encouraged to apply a mixture of herbicide chemicals to control weeds in Roundup Ready® crops (Monsanto, 2010). These residual weed management herbicides are applied either as a tank mix or in sequential applications in the field (Monsanto, 2010; Ross and Childs, 2011; Norsworthy et al., 2012). Table 16 lists approved glyphosate tank mix partners and shows their MOA to illustrate common weed control strategies currently available to soybean growers.

Table 16. Tank mix partners with glyphosate for application to Roundup Ready® Soybean.

Trade Name	Active Ingredient(s)	Mode of Action	Trade Name	Active Ingredient(s)	Mode of Action
2,4-D	2,4-D	Synthetic Auxin	**Lorox**	Linuron	Photosystem II inhibitor
AIM	Carfentrazone-	PPG inhibitor	**Lorox Plus**	Linuron	Photosystem II

	ethyl				inhibitor
Assure II	Quizalofop-P	ACCase inhibitor	**Mee-too-Lachor**	S-metolachlor	Mitosis inhibitor
Authority First	Cloransulam-methyl, sulfentrazone	ALS inhibitor, PPG inhibitor	**Metolachlor**	S-metolachlor	Mitosis inhibitor
Authority MTZ	Cloransulam-methyl, sulfentrazone	ALS inhibitor, PPG inhibitor	**Micro-Tech**	Alachlor	Mitosis inhibitor
Axiom	metribuzin	Photosystem II inhibitor	**Outlook**	dimethenamid	Mitosis inhibitor
Blanket	Sulfentrazone	PPG inhibitor	**PARRLAY**	S-metolachlor	Mitosis inhibitor
Boundary	S-metolachlor	Mitosis inhibitor	**Pendimax**	pendimethalin	Mitosis inhibitor
Canopy	Chlorimuron-ethyl, tribenuron-methyl, metribuzin	ALS inhibitor, ALS inhibitor, Photosystem II inhibitor	**Pendimeth-alin**	pendimethalin	Mitosis inhibitor
Classic	Chlorimuron-ethyl	ALS inhibitor	**Pursuit**	Imazethapyr	ALS inhibitor
Cobra	Lactofen	PPG inhibitor	**Pursuit Plus**	Imazethapyr, pendimethalin	ALS inhibitor, Mitosis inhibitor
Command	Clomazone	Carotenoid biosynthesis inhibitor	**Python**	metribuzin	Photosystem II inhibitor
Command XTra	Clomazone	Carotenoid biosynthesis inhibitor	**Reflex**	Fomesafen	PPG inhibitor
Domain	Metribuzin, flufenacet	Photosystem II inhibitor, Mitosis inhibitor	**Resource**	Flumiclorac	PPG inhibitor
Dual II Magnum	S-metolachlor, benoxacor	Mitosis inhibitor (benoxacor is not classified)	**Scepter**	Imazaquin	ALS inhibitor
Dual MAGNUM	S-metolachlor	Mitosis inhibitor	**Select**	Clethodim	ACCase inhibitor
FirstRate	Cloransulam-	ALS inhibitor	**Select MAX**	Clethodim	ACCase

	methyl				inhibitor
FlexStar	Fomesafen	PPG inhibitor	**Sencor**	metribuzin	Photosystem II inhibitor
Frontier	dimethenamid	Mitosis inhibitor	**S-metolachlor**	S-metolachlor	Mitosis inhibitor
Fusion	butroxidim	ACCase inhibitor	**Spartan**	sulfentrazone	PPG inhibitor
Gangster	Cloransulam-methyl	ALS inhibitor	**Squadron**	Imazaquin, pendimethalin	ALS inhibitor, Mitosis inhibitor
Gauntlet	Flumioxazin, cloransulam	PPG inhibitor, ALS inhibitor	**Steel**	Imazaquin, Imazethapyr	ALS inhibitor
INTRRO	Alachlor	Mitosis inhibitor	**Treflan**	trifluralin	Mitosis inhibitor
Lexone	metribuzin	Photosystem II inhibitor	**Valor**	Flumioxazin	PPG inhibitor
Linex	Linuron	Photosystem II inhibitor	**Valor XLT**	Flumioxazin, Chlorimuron-ethyl	PPG inhibitor, ALS inhibitor
Linuron	Linuron	Photosystem II inhibitor			

Source: (Senseman, 2007; Monsanto, 2010).

Isoxaflutole is currently registered for control of broadleaf and grass weeds in corn as a preplant (surface-applied or incorporated) or preemergence herbicide(Bayer, 2011b). Acreage treated with isoxaflutole varies by year; Table 17 provides a summary of reported applications of isoxaflutole, illustrating the range of reported application rates and total pounds applied across years (USDA-NASS, 2011a). Currently the only use of isoxaflutole on soybeans is under an Experimental Use Permit (EPA, 2010c).

Table 17. Isoxaflutole usage in corn across all program states.

Reporting Year[2]	Total Applied (thousand pounds)	Rate per Application (pounds per acre)	Rate per Crop Year (pounds per acre)	Area Applied (percent)
2010	399	0.065	0.066	7
2005	233	0.051	0.053	6
2003	321	0.060	0.060	8
2002	331	0.070	0.070	9
2001	439	0.070	0.070	9
2000	171	0.070	0.070	3
1999	213	0.080	0.080	4

Source: (USDA-NASS, 2011a)

Notes: Survey states:

1999: Colorado, Illinois, Iowa, and Nebraska.

2000: Illinois, Indiana, Iowa, Nebraska, Ohio, and South Dakota.
2001: Illinois, Indiana, Iowa, Kansas, Nebraska, Ohio, and South Dakota.
2002: Illinois, Indiana, Iowa, Nebraska, and Ohio.
2003: Colorado, Illinois, Indiana, Iowa, Kansas, Nebraska, Ohio, Pennsylvania, South Dakota, and Texas.
2005: Illinois, Indiana, Iowa, Kansas, Kentucky, Missouri, Nebraska, Ohio, Pennsylvania, South Dakota, and Texas.
2010: Colorado, Illinois, Indiana, Iowa, Kansas, Kentucky, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Texas.

Figure 11 illustrates the mean annual use of isoxaflutole in the United States in the 2002 Census of Agriculture crop reports. Figure 12 shows the acreage of soybeans planted in 2011. Note that the historical use of isoxaflutole and current soybean acreage align very closely.

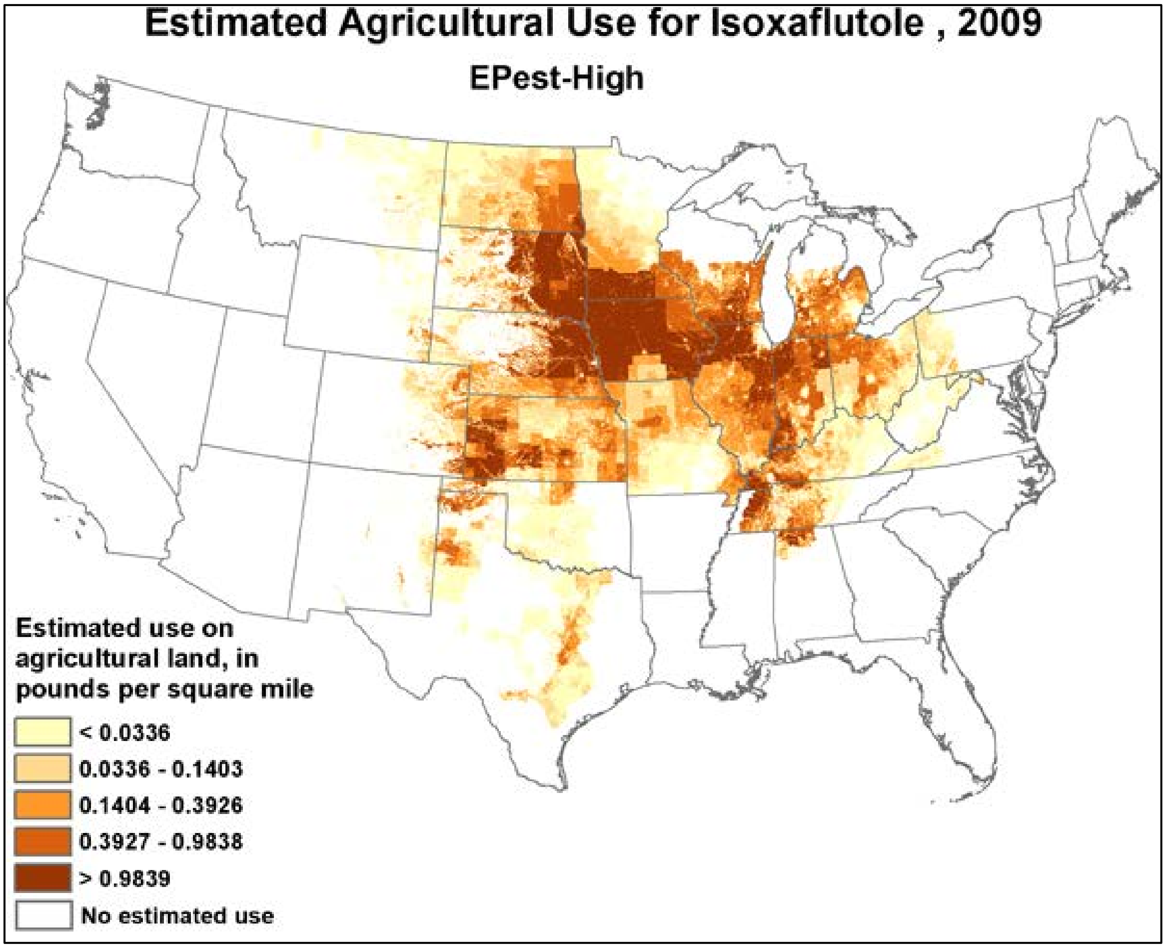


Figure 11. Estimated 2009 annual agricultural use of isoxaflutole in the United States.
Source: (USGS, 2009a).

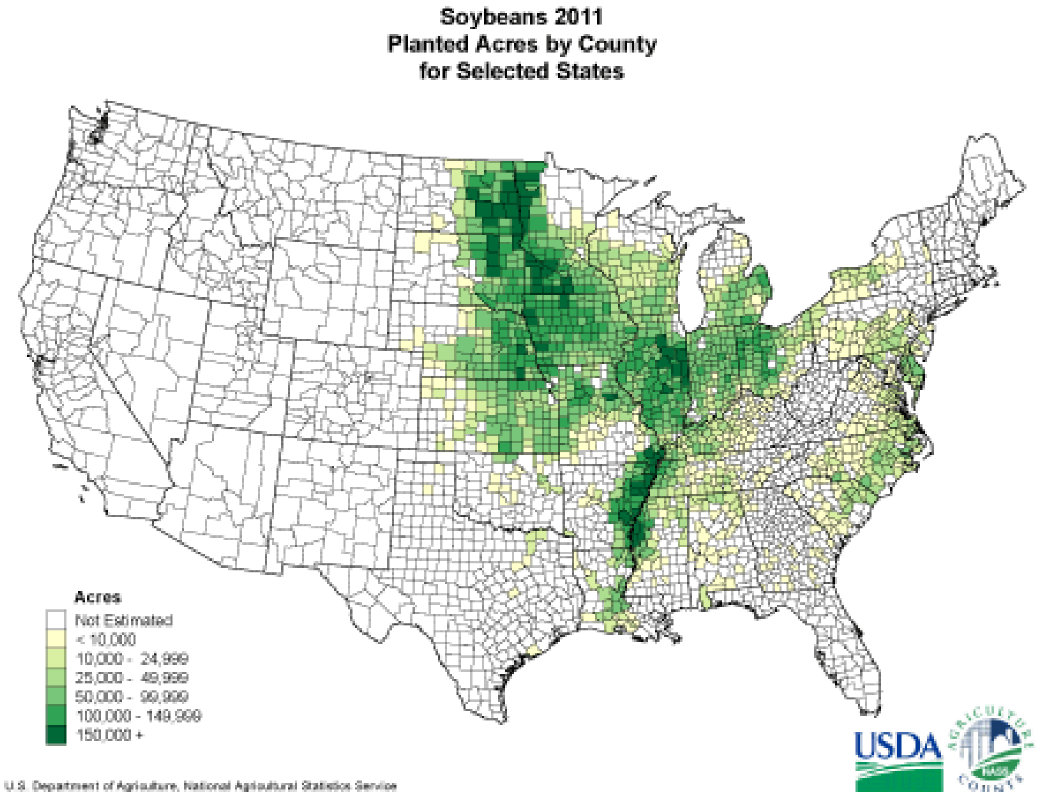


Figure 12. Soybean acreage by county in the United States in 2011. **Source: (USDA-NASS, 2012d).**

Glyphosate is applied to many different crops, including crops in rotation with soybean. Table 18 provides a brief summary of glyphosate applications to crops cultivated in rotation with soybean, identifying the percentage acreage treated, the average number of applications, the amount applied per year per acre, and the total application applied per year.

Table 18. Summary of glyphosate application, by year and crop, for crops in the soybean rotation cycle for the highest reported % acreage treated.

Crop[1, 2]	Reporting Year[3]	% Treated Acres[4]	Maximum Average a.i. per year in lbs/acre[5]	Total a.i. lbs/year (000)[6]
Asparagus	2010	46%	1.27	16.9
Barley	2003	19%	0.53	480.0
Broccoli	2004	1%	1.07	3.0
Cabbage	2004	3%	0.84	2.0
Corn - All[7]	2010	66%	1.06	57,536.0
Corn – Fresh	1998	7%	1.30	13.3

Cotton – Upland[7]	2010	91%	1.70	14,350.0
Cucumbers	2002	13%	1.59	8.7
Hay – Alfalfa and Alfalfa Mixture	1998	<1%	0.51	38
Lettuce	1998	4%	0.84	6.3
Melons - Canteloupe	1996	8%	0.53	3.6
Oats – all	2005	5%	0.60	NR[8]
Onions - bulb	2004	21%	0.79	22.0
Peanuts – all	2004	18%	0.80	187.0
Peas – Green	2004	10%	0.60	11.0
Peppers - Bell	1996	18%	1.28	4.1
Potatoes – Fall[7]	2010	9%	0.79	53.0
Pumpkins – all	2006	24%	1.21	12.0
Rice – rough – all	2006	23%	0.96	630.0
Sorghum – all	2003	27%	0.81	1,823.0
Soybeans – all	2006	92%	1.330	88,903
Squash - all	2004	7%	1.34	4.0
Strawberries – all	2002	7%	0.90	2.5
Sugar beets - All	2000	13%	0.43	86.0
Sunflower Seed – all	1999	14%	0.59	237.0
Tomatoes - Fresh	2000	7%	1.15	9.0
Tomatoes – Processed	1998	54%	0.68	116.8
Wheat - Durum	2006	47%	0.39	319.0
Wheat – Other Spring	2006	30%	0.62	2757.0
Wheat - Winter	2006	15%	0.963	5078.0

Source: (USDA-NASS, 2011c; USDA-NASS, 2011a)

Notes:

1. Only the highest reported years are presented in this table for all reporting program states.
2. Glyphosate use data is available for many other crops, including a large number of tree-nuts and stone-fruits. Because these woody species are unlikely to be cultivated in rotation with soybean, this information was not presented.
3. Reporting years are as provided in the on-line data set provided by the USDA-NASS. The data presented reflects the Agricultural Chemical Usage Summary, with the most recent data in this dataset limited to 2010. Not every crop was reported for every year.
4. % Treated Acres presents only the highest recorded percentage of total acreage treated with glyphosate, and the year in which this record was reported.
5. A.I. – active ingredient; maximum a.i in the surveyed year.
6. Total pounds per year provided only for the highest % year of treated acreage.
7. 2010 data reported in USDA-NASS QuickStats,(USDA-NASS, 2011a).
8. NR – Not reported

Despite the use of isoxaflutole since its registration in 1997 (EPA, 1998), there are few reports of weeds resistant to this herbicide. Since its registration isoxaflutole has not been applied to more than 9 percent of corn acreage in any given year (table 17). The implications of herbicide weed resistance are discussed further in Subsection 4.4.2 – Plant Communities. Although there are few reports of weed resistance to isoxaflutole as compared with reports of weeds resistant to glyphosate, there are reports of weed biotypes resistant to both glyphosate and isoxaflutole and 4-HPPD inhibitors (Heap, 2013). Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska corn fields and two populations of Palmer amaranth in Kansas and Nebraska corn and sorghum fields were reported to be resistant to 4-HPPD inhibitors (Heap, 2013). While the two population of Palmer amaranth and three of the populations of common waterhemp were resistant to 4-HPPD inhibitors they were not specifically resistant to isoxaflutole. However, cross-family resistance to isoxaflutole may be possible. One example of this was found in 2011 in a common waterhemp biotype from Iowa that displayed cross-family resistance to 4-HPPD inhibitors and specifically to isoxaflutole (Heap, 2013).Table 19 lists soybean weeds resistant to glyphosate and 4-HPPD inhibitors as of January, 2013, showing the instance of resistance to herbicides with multiple MOAs. This cross resistance highlights the challenges in managing weeds resistant to herbicides with multiple MOAs. Growers must adapt their weed management strategies, including herbicide use practices, when confronted with herbicide resistant weeds (Norsworthy et al., 2012). Under the No Action Alternative, these trends in agronomic input management by soybean growers are expected to continue.

Table 19. Glyphosate- and isoxaflutole-resistant weeds through January, 2013.

Weed Species	Problem Soybean Weed[1]	Herbicide and Year Resistance Identified			
		Glyphosate-resistant	Year Resistance Identified	4-HPPD Resistant	Year Resistance Identified
Palmer amaranth (*Amaranthus palmeri*)	X	X	2005	X	2009
Spiny Amaranth (*Amaranthus spinosus*)		X	2012		
Common waterhemp (*Amaranthus tuberculatus syn. rudis*)	X	X	2005	X	2009[2]
Common ragweed (*Ambrosia artemisiifolia*)		X	2004		
Giant ragweed (*Ambrosia trifida*)	X	X	2004		
Hairy fleabane (*Conyza bonariensis*)		X	2007		
Horseweed, marestail (*Conyza canadensis*)	X	X	2000		
Junglerice (*Echinochloa colona*)		X	2008		
Goosegrass (*Eleusine indica*)	X	X	2011		
Kochia (*Kochia scoparia*)		X	2007		
Italian ryegrass (*Lolium multiflorum*)		X	2004		
Rigid ryegrass (*Lolium rigidum*)		X	1998		
Annual bluegreass *(Poa annua)*		X	2010		
Johnson grass (*Sorghum halepense*)	X	X	2007		

Source: (Heap, 2013)

Notes: 1. Common weeds in soybean identified pursuant to Johnson et al. (Johnson et al., 2010).
2. Isoxaflutole resistance found in 2011 in Iowa.

Preferred Alternative: Pest Management

General trends related to soybean pest management are unlikely to change under the Preferred Alternative. Bayer field trial data demonstrates that FG72 soybean has very similar agronomic properties to other similar varieties (Bayer, 2011c). Insecticide and fungicide application practices are not expected to change from current management practices, as FG72 soybean is not more susceptible to insect herbivory or fungal diseases than conventional soybean varieties (USDA-APHIS, 2012d).

As described in the no action alternative, growers are encouraged to apply herbicides with multiple MOAs as part of an integrated weed management program (Norsworthy et al., 2012; Shaw et al., 2012). As noted in Table 19 above, glyphosate-resistant weeds have been identified in soybeans. FG72 soybean provides growers with the ability to apply isoxaflutole as part of their integrated weed management program. Grower trends to apply herbicides with multiple MOAs are the same as those currently implemented under the no action alternative.

Herbicide use trends in U.S. soybean production are not anticipated to be substantially affected following a determination of nonregulated status of FG72 soybean, although the specific application of isoxaflutole to soybean provided by this variety is a change within the trends. FG72 soybean is resistant to both glyphosate and isoxaflutole. Accordingly, FG72 soybean may be integrated into current soybean pest management practices using glyphosate, allowing glyphosate-use trends to continue at rates comparable to the No Action Alternative. Additionally, while not previously used in soybean production, isoxaflutole represents an alternative herbicide available to U.S. soybean growers. The herbicide resistant crops planted thus far have altered the mix of herbicides used in cropping systems and allowed the substitution of glyphosate for other herbicides (NRC, 2010b). Despite this trend the diversity of used herbicides has increased since 1995 (USDA-NASS, 1996; USDA-NASS, 2002b; USDA-NASS, 2007b). The potential use of isoxaflutole on FG72 soybean does not represent a shift from this herbicide diversity trend.

The use of isoxaflutole in U.S. soybean production will increase under the Preferred Alternative. This is an expected outcome, as isoxaflutole was not previously utilized in U.S. soybean production (EPA, 2011g). Current use of isoxaflutole in field corn suggests that use in soybean may not be substantial. Isoxaflutole has not been applied to more than 9 percent of field corn since commercial introduction in 1999 (Table 17). In 2010, isoxaflutole use in field corn totaled 399,000 lbs. applied to 7 percent of corn acres; this value was much less than total glyphosate use at 57,536,000 lbs. applied to 66 percent of corn acres (USDA-NASS, 2011a). Isoxaflutole is used at 10 percent the rate of glyphosate on corn (USDA-NASS, 2011b; USDA-NASS, 2011a).

The most likely growers to adopt FG72 soybeans would be those growers currently using isoxaflutole on corn. Bayer's internal market research projected adoption rates of isoxaflutole herbicide for weed control in FG72 soybean crops (Table 20)(Weeks, 2013). FG72 soybeans will reach their maximum adoption rate in 2019 with 4 million acres of FG72 soybeans planted and treated with isoxaflutole (Weeks, 2013). Despite the increased use of isoxaflutole in U.S. soybean production, there will not be a substantial increase in the environmental impacts as compared to the No Action Alternative for several reasons.

Table 20. Projected Adoption of Isoxaflutole use in FG72 Soybean

Year	**Isoxaflutole Treated FG72 (million acres)**	**Isoxaflutole Treated FG72 as % of average US Annual Soybean Planted Acres, 2009-2013[3]**
2016[1]	0.3	0.4
2017	2.6	3.4
2018	3.3	4.3
2019[2]	4.0	5.2

Source: (Weeks, 2013)
[1]Anticipated year of FG72 product launch
[2]Projected year of maximum adoption of Bayer CropScience isoxaflutole herbicide use in event FG72 soybean
[3]US soybean planted acres accessed from USDA NASS. Quick Stats 2.0. Retrieved June, 2013 from United States Department of Agriculture. http://quickstats.nass.usda.gov

First, isoxaflutole is classified as a restricted use pesticide (EPA, 2011c). Isoxaflutole may only be applied by a certified applicator or under the direct supervision of a certified applicator in specific agroenvironments and in a certain number of states, thus potentially precluding its common and widespread adoption in soybeans (EPA, 2012f). Certified applicators are more likely to carefully follow the label restrictions since violators of requirements are liable and can be held legally accountable for all negative consequences of their actions. Second, as a pre-emergent/early post-emergent herbicide, isoxaflutole application is restricted to a short application timeframe in the beginning of a soybean growing season. This limited application window, coupled with restrictions on annual use (no more than one application per growing season, Appendix A) and reduced application rates relative to other common soybean herbicides (Table 21), suggests that isoxaflutole adoption rates in soybeans will be limited.

Lastly, despite the increase in use of isoxaflutole it will still be relatively limited in use when compared to other herbicides. Bayer's estimate of maximum adoption on 4 million acres by 2019 would represent 5.2 percent of the U.S. total soybean acres (Weeks, 2013). As noted above in Table 5 this would place isoxaflutole eleventh among herbicides used in soybean. In addition to this relatively low adoption rate in soybean the application rate of isoxaflutole is also low compared to other commonly used herbicides (Table 21).

Table 21. Maximum soybean herbicide application rates (single and annual application).

Herbicide Active Ingredient	Rate/Application (lbs./acre)	Rate/Crop Year (lbs./acre)
2,4-D, 2-EHE	0.493	0.503
2,4-D, BEE	0.426	0.459
2,4-D, dimeth. salt	0.462	0.475
Acifluorfen, sodium	0.287	0.296
Alachlor	1.931	1.931
Bentazon	0.687	0.687
Carfentrazone-ethyl	0.038	0.046
Chlorimuron-ethyl	0.017	0.017
Clethodim	0.096	0.102
Cloransulam-methyl	0.019	0.019
Dicamba, digly salt	0.25	0.25
Fenoxaprop	0.031	0.031
Fluazifop-P-butyl	0.099	0.099
Flufenacet	0.265	0.265
Flumetsulam	0.048	0.048
Flumiclorac-pentyl	0.02	0.028
Flumioxazin	0.066	0.066
Fomesafen	0.19	0.233
Glyphosate	0.63	1.044
Glyphosate amm. salt	0.489	0.745
Glyphosate iso. salt	0.802	1.33
Imazamox	0.03	0.03
Imazaquin	0.061	0.062
Imazethapyr	0.053	0.053
Imazethapyr, ammon	0.048	0.048

Herbicide Active Ingredient	Rate/Application (lbs./acre)	Rate/Crop Year (lbs./acre)
Isoxaflutole	0.07	0.07
Lactofen	0.11	0.11
Metribuzin	0.255	0.26
Paraquat	0.492	0.511
Pendimethalin	0.92	0.926
Quizalofop-P-ethyl	0.038	0.041
S-Metolachlor	1.023	1.023
Sethoxydim	0.153	0.153
Sulfentrazone	0.087	0.091
Sulfosate	0.967	1.701
Thifensulfuron	0.004	0.004
Tribenuron-methyl	0.008	0.008
Trifluralin	0.818	0.818

Source: USDA-NASS (2002b; 2007b).

As described in the No Action Alternative, total herbicide use may increase in U.S. soybean production due to farm-level response to glyphosate-resistant weeds (NRC, 2010b). A determination of nonregulated status of FG72 soybean would likely contribute to this trend, as it would facilitate the use of an herbicide not previously used in U.S. soybean production. The overall trends associated with grower utilization of herbicides with multiple MOAs for weed management are the same as those in the No Action Alternative. The contribution of isoxaflutole to soybean total herbicide use is likely to be small, due to its use restrictions and reduced application rates (single and annual rate) relative to other common soybean herbicides. Isoxaflutole use on soybean is expected to increase, and the total volume of isoxaflutole applied in U.S. soybeans could potentially reach 5.4 percent of the soybean acres (Weeks, 2013). However, isoxaflutole use will remain at low adoption rates due to its restricted use conditions. Glyphosate use, and the percentage of acres treated with glyphosate are not projected to change. Based on these findings, there are no substantial differences between the no action alternative and the preferred alternative.

4.3 Physical Environment

4.3.1 Soil Quality

No Action Alternative: Soil Quality

Under the No Action Alternative, current soybean management practices would be expected to continue. Agronomic practices that benefit soil quality, such as contouring, use of cover crops to limit the time soil is exposed to wind and rain and introduce certain soil nutrients, crop rotation, and windbreaks would not change as a result of the continued regulated status of FG72 soybean.

Soil quality in the agroenvironment is influenced by a variety of agronomic practices, including the crop cultivated and its associated management practices. In particular, tillage is strongly correlated with soil quality (NRC, 2010a). As discussed in Section 4.2.2, conservation tillage in U.S. soybean is generally associated with 30 percent or greater remaining plant residue and reduced soil erosion and compaction. The use of conservation tillage in U.S. soybean production has increased, an effect attributed to the glyphosate-resistant soybean system. As noted above in section 4.2.2, in response to the emergence of glyphosate-resistant weeds, growers often have returned to conventional tillage systems to control these weeds. For example, growers managing glyphosate-resistant Palmer amaranth (*Amaranthus palmeri*) and Horseweed (or marestail, *Conyza canadensis*) have been reported to revert to conventional tillage systems in order to obtain effective control (Steckel and Montgomery, 2008; Price et al., 2011). Several researchers acknowledge that glyphosate-resistant weeds pose the greatest threat to conservation tillage, noting that some growers have eliminated conservation tillage because tillage was the only effective control (Price et al., 2011; Shaw et al., 2012). Consequently, because of the strong relationship between conservation tillage and soil quality (Holland, 2004), soil quality in soybean fields may be affected as a consequence of continued development of glyphosate resistant weeds and an increased need for conventional tillage.

Soil quality may also be affected by the addition of pesticides. Under the No Action Alternative, insecticide use will remain as it is currently practiced and limited to a small percentage of total U.S. soybean acreage (USDA-NASS, 2007a). Growers likely would still experience the continued emergence of glyphosate-resistant weeds, requiring a diverse weed management strategy, including use of herbicides with multiple MOAs to address these weeds. Glyphosate is anticipated to remain the most widely-applied herbicide in U.S. soybean production, however, the use of alternative herbicides may increase to meet the need for additional integrated weed management tactics to mitigate herbicide-resistant weeds in different cropping systems (Owen and Zelaya, 2005; Culpepper et al., 2008; Owen, 2008; Heap, 2013). Some of these adjustments may have the potential to impact soil quality.

Preferred Alternative: Soil Quality

Soil quality in U.S. soybean production fields is unlikely to be substantially affected under the Preferred Alternative. The increasing adoption of conservation tillage has been partially enabled by the capacity to apply a broad-spectrum herbicide [glyphosate] over a resistant variety [glyphosate-resistant soybean]. FG72 soybean is resistant to glyphosate and isoxaflutole, both broad-spectrum herbicides. Thus, conservation tillage trends, and its direct effects on soil quality, are likely to continue.

A consequence of conservation tillage is the incorporation of plant material from the preceding crop into the soil (CTIC, 2008). Consequently, any changes in remaining plant tissue from previous growth may affect soil quality. However, FG72 soybean plant material is unlikely to substantially affect soil quality, as compositional analysis of FG72 soybean tissue demonstrates that it is not substantially different from its non-GE parent variety, Jack (Bayer, 2011c; USDA-APHIS, 2012d).

Under the Preferred Alternative, glyphosate and isoxaflutole may be applied to the soil during FG72 cultivation. Glyphosate use has been reviewed in previous APHIS documents and is not anticipated to negatively affect soil quality, when it is used in accordance with the EPA restricted use label (USDA-APHIS, 2012c). Isoxaflutole, at present, has been primarily applied on field corn. As described in Appendix C, isoxaflutole yields a diketonitrile and benzoic acid derivative through biotic or abiotic processes. Isoxaflutole itself is not likely to substantially affect soil quality, as degradation of isoxaflutole is generally rapid, resulting in a half-life of only 0.5 – 13.9 days across a variety of soil types (Beltrán et al., 2002; Papiernik et al., 2007; EPA, 2011b). Furthermore, the estimated half-life of diketonitrile is 61 days, facilitated by aerobic soil metabolism (EPA, 1998). Diketonitrile is the bioactive principle of isoxaflutole, and thus, may be responsible for non-target plant injury that may result from growth on the treated soil. However, EPA label use restrictions on isoxaflutole formulations places minimum limits on when another crop may be planted following isoxaflutole application. These intervals, ranging from 4-18 months, exceed the half-life of diketonitrile and are designed to mitigate any incidental plant injury from the soil (Bayer, 2011b). As a consequence of its registration of isoxaflutole, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying isoxaflutole herbicide formulations.

4.3.2 Water Resources

No Action Alternative: Water Resources

Under the No Action Alternative, water resources associated with soybean production is not likely to be substantially affected. As discussed in Subsection 2.2.2 – Water Resources, The soils and climate in the Midwest, Southeast, and Eastern Coastal regions provide sufficient water supplies under normal climatic conditions to produce a soybean crop. The general water requirement for a high-yielding soybean crop is approximately 20 to 24 inches of water during the growing season to produce a relatively high yield of 40-50 bushels per acre (KSU, 1997; Hoeft et al., 2000). In 2006, when 8.6% of the total soybean crop was irrigated, over 92% of the irrigation supply was from groundwater supply (USDA-ERS, 2013c). In 2006, irrigated soybean produced an average of 51 bushels per acre, where the national average for that year was 42.9 bushels per acre (USDA-NASS, 2013e).

As discussed in Subsections 2.2.2 and 4.2.2 – Agronomic Practices , herbicide-resistant soybeans, cultivated on 93 percent of soybean acreage, have resulted in the adoption of increased conservation practices (NRC, 2010b; USDA-ERS, 2011a). These conservation practices, including reduced tillage and precision agriculture, play a major role in water conservation and maintaining water quality by minimizing soil erosion (USDA-NRCS, 2006). In 2008, approximately 63% of soybean growers had adopted conservation tillage practices, including no-till through reduced-till conserving 15-30% of residues (CTIC, 2008; NRC, 2010a). In 2011, 65% of U.S. soybean acres reported some form of conservation tillage (USB, 2011b). Intensive monitoring of surface water and groundwater proximate to agricultural fields has demonstrated that conservation tillage practices can reduce runoff from agricultural lands, decreasing NPS pollution of suspended sediment, nutrients from fertilizers, and pesticides (University of Tennessee Agricultural Extension Service, 2011). Better nutrient management, including integration of IPM techniques that minimize pesticide movement from the field, are ensuring inputs are used by the crop and are not entering ground or surface waters (EPA, 2005). As discussed previously, conservation tillage trends are not expected to change in U.S. soybean production from what is currently practiced; accordingly, the impacts of conservation tillage on water resources are also expected not to change.

The EPA considers water resources, groundwater, surface water and drinking water, and potential contamination of water resources, when registering a pesticide under FIFRA. Precautions to protect water resources, including aquatic animals and plants, if required, are provided on the pesticide label.

Isoxaflutole is currently registered for use in field corn for the control of a wide range of grass and broadleaf weeds. After initial review in 1997 isoxaflutole was determined to have properties and characteristics associated with chemicals detected in ground water. It was determined that isoxaflutole residues and its degradates could potentially contaminate surface and ground waters. To prevent damage to crops and other desirable plants, EPA implemented label use restrictions (EPA, 1998). During the ecological assessment for use on soybeans in 2010, the EPA considered the potential risks of isoxaflutole use to surface and groundwater using screening simulation models[29] to estimate environmental concentrations in surface and groundwater (EPA, 2010d). These models use known physical, chemical and environmental properties of the herbicide as well as label approved application rates (EPA, 2010d). Since the primary transformation product of isoxaflutole, diketonitrile is potentially toxic to humans and exhibits a greater persistence and potential mobility than the parent, it was also included in the surface and ground water assessments using the screening models (EPA, 2010d; EPA, 2011h). The EPA then compares these modeled exposures with ecotoxicity studies to determine whether the proposed pesticide use could result in impacts to human health or the environment (EPA, 2010d). For drinking water estimates, the EPA considered acute and chronic toxicity studies (EPA, 2010d; EPA, 2011h). The EPA found that for surface and ground water sources, isoxaflutole exposures were below the agency's level of concern for all population subgroups (EPA, 2011h).

Although isoxaflutole is mobile and is assumed to have limited potential to volatilize, rapid degradation in both soil and water reduces the potential for parent isoxaflutole to be transported to either surface or ground water (EPA, 2001; EPA, 2010d). Through physical and chemical action, isoxaflutole degrades quickly into two compounds, the primary metabolite, diketonitrile, and the terminal metabolite, RPA 203328 (benzoic acid) , which has no herbicidal activity(EPA, 2010d). Isoxaflutole is not expected to persist in surface water or to reach groundwater(EPA, 2001) however, the metabolite diketonitrile is expected to reach both ground and surface water, where it is expected to persist and accumulate (EPA, 2001). Contamination of the surface waters by diketonitrile has been amply demonstrated by the monitoring program required under the conditional registration (EPA, 2010d).

Runoff from soybean and/or corn fields may contain residues of isoxaflutole parent and its phytotoxic degradate, diketonitrile. These waters if used for irrigation on non-target plants (crops) may exceed the EPA's level of concern for non-target plants (EPA, 2011h). However, EPA's level of concern was not exceeded for aquatic non-target plants, birds, mammals, fish, or invertebrates (EPA, 2011h). The acute, chronic, and cancer aggregate exposure and risk estimates were also found to be not of concern (EPA, 2011d).

---

[29] Screening simulation models are used by the EPA to estimate the highest potential exposures across various environmental pathways. For pesticide exposures, this includes using highest application rates and maximum acreage, generating very conservative (i.e. protective) model outputsEPA, Ecological Risk Assessment for the Isoxalfutole Proposed Section 3 Registration for Use on Soybeand and on Corn in Five Additional Southern States (South Carolina, Georgia, Alabama, Mississippi, and Louisiana). (Washington DC: Environmental Protection Agency, 2010d)..

The EPA has found that pesticides, in general, are relatively minor contributors to impairment of surface water (EPA, 2013c). Of the pesticides that were reported as contributing to impairment among the leading soybean-producing states, almost all are highly persistent chemicals that are no longer registered for use in the United States (EPA, 2013c). Glyphosate and Isoxaflutole are not included on this list.

Label restrictions have been imposed to protect sensitive water bodies (Appendix A and (Monsanto, 2010). The EPA has considered the potential impacts to water resources from the agricultural application of isoxaflutole, and has included label use restrictions and handling guidance intended to prevent impacts to water. For example, label restrictions for Balance PRO®, specific to water resources include, prohibiting applications directly to water or areas where surface water is present, managing proper disposal of equipment wash water, restrictions on methods of application, and state specific restrictions regarding soil types and depth to the water table (Appendix A). The implications of animal exposure to isoxaflutole in the aquatic environment are discussed in Subsection 4.4.1 – Animal Communities.

The following ground water advisory is required on all labels containing isoxaflutole: This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Thus, use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination (EPA, 2010d).

The following surface water advisory is required on all labels containing isoxaflutole: Isoxaflutole residues can contaminate surface water through spray drift. Under some conditions, isoxaflutole residues may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips and areas over-laying tile drainage systems that drain to surface water.(EPA, 2010d)

As noted in Section 2.1 – Agricultural Production of Soybean, glyphosate is currently widely used in American agriculture, including soybeans and crops in the soybean rotation. EPA label restrictions are currently in place to minimize potential impacts to water (see e.g., (Monsanto, 2010). The use of glyphosate on soybeans and other rotational crops will not change under the No Action Alternative.

Under the No Action Alternative, current land acreage and agronomic practices, including irrigation, tillage, and nutrient and pesticide management associated with U.S. soybean production would not be expected to change. No expected changes to water quality beyond current trends associated with soybean production are expected for this Alternative.

<u>Preferred Alternative: Water Resources</u>

Under the Preferred Alternative, no substantial impact to water resources is anticipated from a determination of nonregulated status of FG72 soybean.

A determination of nonregulation for FG72 soybean would provide growers with the option to consider applying isoxaflutole as part of a weed management strategy employing herbicides with multiple MOAs. This strategy is consistent with current practices and recommendations for managing herbicide resistant weeds (Owen et al., 2011c; Norsworthy et al., 2012). As noted in Subsection 4.2.2 – Agronomic Practices, avoiding tillage provides an immediate benefit to water resources associated with the consequent minimization of soil erosion. Cultivation of FG72 soybean is likely to permit the continued use of conservation tillage as it is currently practiced, and its effects on water resources through the mitigation of water loss and runoff attributes, is not expected to be substantially different from the No Action Alternative.

With regard to irrigation, Bayer's field trial results demonstrated no differences in morphological characteristics and agronomic requirements between FG72 soybean and its non-transgenic parent variety, Jack (Bayer, 2011c; USDA-APHIS, 2012d). This implies that FG72 soybean does not require more moisture. Therefore, its irrigation requirements will not differ substantially from that of soybean varieties that are commercially available (Bayer, 2011c; USDA-APHIS, 2012d). Also, as previously discussed in Subsection 4.2.1 – Range and Acreage of Soybean Production, the use of FG72 soybean would not increase the total acres and range of U.S. soybean production areas. Accordingly, the consequences of the Preferred Action Alternative on water use in soybean production are the same as the No Action Alternative. Therefore, a determination of nonregulated status of FG72 soybean is unlikely to change the current use of irrigation practices in commercial soybean production compared to the No Action Alternative.

Under the Preferred Alternative, glyphosate and isoxaflutole may be applied on FG72 soybean. Glyphosate is applied to most U.S. soybean acreage (Dill, 2005); it will likely be applied to FG72 soybean following a determination of nonregulated status. Glyphosate use has been reviewed in previous APHIS documents and is not anticipated to negatively affect water resources when it is used in accordance with the EPA restricted use label (USDA-APHIS, 2012b). With regard to isoxaflutole application, degradation occurs rapidly in both soil and aqueous environments (Beltrán et al., 2002; Taylor-Lovell et al., 2002; Rice et al., 2004). Thus, isoxaflutole is not expected to persist in groundwater (aquifers) or surface water (EPA, 2001; DATCP, 2002), with detection only occurring shortly after field application (Scribner et al., 2006).

The application rates, and total annual herbicide applications are consistent with previous EPA risk assessment analyses conducted in the reregistration document (see e.g., (EPA, 1998). APHIS assumes that EPA will revisit potential water exposure and corresponding impacts as part of their analysis of the proposed label change, and that if additional label use restrictions are required, these use limitations will be incorporated in a new label. EPA labels for isoxaflutole restrict its use to areas and soil types where it will not contaminate ground and surface water. APHIS further assumes that any isoxaflutole use will be conducted consistent with these label restrictions minimizing risks to ground and surface waters.

Diketonitrile , the bioactive principle of isoxaflutole, is relatively stable and more mobile in the aqueous phase than parent isoxaflutole (EPA, 2011g). Laboratory and tile-drain studies demonstrated the relative stability of diketonitrile in aqueous environments and suggested that it may persist in surface water (DATCP, 2002; EPA, 2011g). Detection of diketonitrile in surface water resources surrounding midwestern corn fields further demonstrated the persistence and mobility of diketonitrile under field conditions (EPA, 2001; EPA, 2002; Rector et al., 2003; Scribner et al., 2006).

Presence of a metabolite in a water resource does not, in itself, represent a negative impact. More relevant is the plausibility and magnitude of an impact. Phytotoxicity risks to non-target terrestrial plants due to the presence of diketonitrile in field runoff and surrounding surface water precipitated the characterization of isoxaflutole as a restricted use pesticide by the EPA (EPA, 2011c). Risk to aquatic plants, birds, mammals, invertebrates, and fish from isoxaflutole and diketonitrile were determined to be below the EPA level of concern, suggesting that the toxicity of isoxaflutole and diketonitrile is relatively low (EPA, 2011c) (Appendix A). Relative to other herbicides applied to U.S. soybean fields, isoxaflutole and its degradates fall within the range of environmental impact quotient (EIQ) for several parameters related to water resources, such as leaching potential, and effects on fish, birds, beneficial organisms, and ecology (Table 22). When compared to other herbicides applied on soybean, isoxaflutole appears to possess an average leaching potential (Table 22). As a consequence of its registration of isoxaflutole, EPA has effectively determined that there is no unreasonable harm to the environmental if the end user adheres to the label use restrictions when applying isoxaflutole herbicide formulations. EPA label directions include application restrictions plus requirement for a certified applicator to minimize effects on nearby environments. Isoxaflutole is currently undergoing a registration review by EPA (EPA, 2011c). If EPA determines that additional restrictions beyond current restrictions (Appendix A) on isoxaflutole use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend isoxaflutole use labels accordingly.

Based on these findings, the potential impacts to water resources are expected to be the same under the Preferred Alternative as under the No Action Alternative.

Table 22. Environmental Impact Quotient (EIQ) of soybean herbicides with respect to several factors related to water resources. Highlighted rows indicate an herbicide that was applied on a percentage of soybean acres greater than 5 percent in 2006. Isoxaflutole is generally not applied on soybean.

Active ingredient	EIQ Review date	Leaching	Fish	Birds	Beneficials	Ecology
2,4-D, 2-EHE	April-04	1	5	6	15	35
2,4-D, dimethyl salt	April-04	5.00	1.00	6.00	15.00	31.00
Chlorimuron-ethyl	April-04	5.00	3.00	6.00	24.60	42.60
Clethodim	Dec-00	5.00	1.00	6.00	15.00	31.00
Cloransulam-methyl	Jan-03	3.00	3.00	6.00	15.00	33.00
Fluazifop-P-butyl	Mar-09	1.00	15.00	4.65	21.00	72.15
Flumiclorac-pentyl	Mar-09	5.00	3.00	9.00	25.20	46.20
Flumioxazin	Dec-05	2.10	10.20	6.00	24.60	49.80
Fomesafen	Mar-09	5.00	1.00	7.65	17.64	32.59
Glyphosate amm. Salt	April-08	1	5	6	15	35
Imazaquin	Mar-09	5.00	1.00	3.00	25.00	32.00
Imazethapyr	Mar-09	5.00	1.00	7.65	17.54	32.49
Metribuzin	Apr-03	5.00	1.00	27.00	32.10	69.10
Paraquat	Mar-09	1.00	5.00	10.65	13.97	35.92

Active ingredient	EIQ Review date	Leaching	Fish	Birds	Beneficials	Ecology
Pendimethalin	Mar-08	1.00	25.00	9.00	30.00	73.00
S-Metoachlor	Jan-03	3.00	9.00	12.00	15.00	45.00
Sulfentrazone	Jan-04	5.00	1.00	9.00	8.20	21.20
Sulfosate	Mar-01	3.00	3.00	9.00	45.00	66.00
Tribenuron-methyl	Apr-04	3.10	3.40	6.00	15.00	33.40
Trifluralin	Apr-08	1.00	25.00	9.00	5.00	42.00
Isoxaflutole	Jan-04	3.00	9.00	6.00	15.00	39.00

Sources: NY State IPM Program (2012) and USDA-NASS (2007b).

4.3.3 Air Quality

No Action Alternative: Air Quality

All agricultural practices have the potential to cause negative impacts to air quality. Agricultural emission sources include smoke from agricultural burning, tillage, heavy equipment emissions, pesticide drift from spraying, and indirect emissions from carbon dioxide and nitrous oxide emissions from the use of nitrogen fertilizer and degradation of organic materials (USDA-NRCS, 2006; Aneja et al., 2009; EPA, 2010f).

Current soybean agronomic practices have the potential to reduce air emissions from several of these sources. Conservation practices, including conservation tillage practices, require fewer tractor passes across a field, thereby decreasing dust generation and tractor emissions. Surface residues and untilled organic matter physically serve to hold the soil in place, thereby decreasing airborne soils and pesticide drift in wind-eroded soils.

Under the No Action Alternative, current impacts to air quality associated with soybean acreage and cultivation practices would not be affected.

Adoption of GE soybean varieties is expected to continue. To the extent that the adoption and cultivation of GE soybean varieties allows the grower to implement soil conservation practices presented in Subsection 4.3.1 – Soil Quality, air quality improvement associated with these practices would be expected to follow. This would include both direct air quality effects, e.g., emissions from farm equipment, airborne soil erosion and pesticide drift, as well as indirect air quality effects, e.g., nitrous oxide emissions associated with the use of nitrogen fertilizers (USDA-NRCS, 2006; Aneja et al., 2009; EPA, 2012b). Air quality will continue to be affected by current agronomic practices associated with conventional methods of soybean production such as tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment.

Off-target drift and volatilization, and attendant injuries to non-target plants has been previously identified as a concern (Jordan et al., 2009; Bayer, 2011b). The EPA considers potential off-site movement of herbicides during the pesticide registration process; to approve herbicide uses, EPA must conclude that no unreasonable adverse effects on non-target vegetation will result from potential offsite movement when the pesticide is used according to the product label (see e.g., (EPA, 2009d). When pesticides are applied in accordance with label instructions, offsite impacts can be avoided. Herbicide applicators are required by law to adhere to these label restrictions, including, in this case, label restrictions intended to minimize off-site movement of the herbicides (Jordan et al., 2009).

After a pesticide is registered by EPA, states can register pesticides under specific state pesticide registration laws (EPA, 2013g). States are permitted to apply more stringent requirements on the use of the pesticide as needed to address specific local considerations, but modifications to the product label in a manner that reduces requirements of the federally approved label are not permitted (EPA, 2013g). States have the primary responsibility to enforce the use of the pesticide product in accordance with the product label, including application requirements that minimize potential off-target impacts (EPA, 2013g).

Isoxaflutole is currently subject to specific use regulations or requirements in four states. Table 13 lists these states where isoxaflutole is registered for use and which ones have further restrictions. Currently isoxaflutole is registered for use in 20 states and has further EPA use restrictions in place in 14 of those states (see Appendix A). Prior to authorizing the use of isoxaflutole on FG72 soybean, state pesticide regulating authorities will review the EPA-approved product label, which includes application requirements to minimize potential impacts of isoxaflutole offsite movement, and other information required by the state. As a part of this process the state regulating agency will determine if new or existing state isoxaflutole regulations or restrictions are necessary before approving the product for use (EPA, 2013d). The incorporation of application requirements in the product label allows the states to enforce these requirements with applicators. Some states may choose to approve the product label without additional regulations or restrictions and monitor incident reports post commercialization to determine if further action is warranted.

APHIS assumes that growers will adhere to these state-specific restrictions. Growers and herbicide applicators currently employ recognized management strategies to manage potential off-target drift and volatilization, including implementing specific pesticide label use restrictions and precautions (see e.g., (Monsanto, 2010; Bayer, 2011b). These practices include selection and calibration of pesticide spray nozzles to generate coarse sprays, maintaining spray pressure at low levels, using drift-reducing nozzles, and incorporating drift-reducing additives to the herbicide mix (SDTF, 1997; Felsot et al., 2011). None of these practices are expected to change under the No Action Alternative.

These strategies are not unique to isoxaflutole, and are considered in other herbicides, including glyphosate (Monsanto, 2010). As noted in Subsection 4.1.2 – Agronomic Practices, glyphosate is currently used on soybeans and its rotational crops. Glyphosate label use restrictions have been imposed to minimize drift (see e.g., (Monsanto, 2010).

Isoxaflutole is currently registered as a restricted use pesticide on corn. Isoxaflutole label use restrictions have been imposed to minimize drift (see e.g., (Bayer, 2011b) and appendix A). These label use restrictions are not expected to change under the No Action Alternative.

Agronomic practices associated with conventional soybean production that contribute to air quality and GHG emissions, including tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment, are not expected to change.

Preferred Alternative: Air Quality

Under the Preferred Alternative, a determination of nonregulated status of FG72 soybean is unlikely to substantially impact air quality compared to the No Action Alternative.

As previously discussed in Section 4.2 – Agricultural Production, FG72 soybean is similar in agronomic performance and likely requires similar cultivation practices as currently-cultivated conventional soybean varieties, and is not likely to change land acreage or any cultivation practices for conventional, transgenic, or non-transgenic soybean production. It is expected that similar agronomic practices (with the exception of isoxaflutole use) commonly utilized in commercially available soybean varieties would also be used by growers of FG72 soybean. Accordingly, a determination of a nonregulated status of FG72 soybean is unlikely to change the use of agricultural practices with the potential to affect air quality from what is currently practiced. In particular, the adoption of conservation tillage is generally increasing in conventional soybean production, partially enabled by the use of effective, non-selective herbicides such as glyphosate. Under the Preferred Alternative, FG72 soybean would also permit the use of two non-selective herbicides (glyphosate and isoxaflutole) that may facilitate conservation tillage. Thus, the effects of tillage on air quality would be maintained and not deviate substantially as it is currently practiced in typical soybean production practices.

General management strategies currently employed to manage and mitigate herbicide drift and volatilization would not differ from those currently employed throughout the industry under the No Action Alternative. Depending upon the site-specific application requirements, growers would continue to select from a range of strategies to reduce drift and volatilization currently provided and enforced on herbicide labels (see e.g.,(Monsanto, 2010; Bayer, 2011b). As discussed in Subsection 4.2.2 – Agronomic Practices, growers and commercial herbicide applicators have been applying isoxaflutole to corn since 1998. This practice has provided valuable experience and knowledge on the proper application of isoxaflutole for effective weed control and also for minimizing offsite movement to sensitive crops. Isoxaflutole underwent an ecological risk assessment in April 2010 for use on soybeans (EPA, 2011b). It is currently under reregistration review, which began in June 2011 and is scheduled for completion in 2017 (EPA, 2011b). This change in use is not expected to have an effect on herbicide drift as growers would continue to utilize strategies to reduce drift as provided on the herbicide label.

Offsite herbicide movement from spray drift depends upon local weather conditions at the time of application (wind, temperature, humidity, inversion potential), spray droplet size distribution, application volume, boom height (height of the application equipment above the target pest or crop canopy), sprayer speed, and distance from the edge of the application area (SDTF, 1997; Felsot et al., 2011). It is not possible to eliminate spray drift, but such drift can be minimized by using best management practices (Felsot et al., 2011). These best management practices include using appropriate nozzle types, nozzle shields, spray pressure, volumes per area sprayed, tractor speed and only spraying when climatic conditions are suitable (Felsot et al., 2011). Field layout can influence spray drift, and spray-free buffer zones and windbreak crops can also have a mitigating effect (Felsot et al., 2011). Spray droplet size has been identified as the most important factor in spray drift (SDTF, 1997). The potential impacts of herbicide drift to non-target plants is a function of the selectivity and sensitivity of the herbicide.

Awareness of the presence of sensitive areas and whether the wind direction at the time of application may move any suspended spray droplets toward a sensitive area are important considerations at the time of application (Hahn et al., 2011). Since the implementation of the DriftWatch™ [30] program in Indiana, drift incidents onto sensitive crops have been remarkably reduced (Hahn et al., 2011). The DriftWatch™ program has now been expanded to several states across the major Midwest soybean growing area (IL, IN, MI, MN, and WI) (Hahn et al., 2011).

As discussed in Subsection 1.1 – Coordinated Framework Review and Regulatory Review, before any application of isoxaflutole can be made onto FG72 soybean, the EPA must first approve the label describing the conditions of use of the herbicide in connection with FG72 soybean – including the appropriate application rates and timing, and other measures necessary to address any potential for isoxaflutole drift and offsite movement. Before the EPA can approve the label changes, the EPA must first reach a conclusion that no unreasonable adverse effects on non-target vegetation will result from drift and offsite movement when isoxaflutole is applied according to the directions for use contained in the label.

The proposed use pattern for isoxaflutole on FG72 soybean is consistent with use patterns evaluated and deemed eligible for reregistration in the isoxaflutole RED; it is reasonable to conclude that isoxaflutole use on FG72 soybean meets the FIFRA standards related to offsite movement and does not pose any greater risk to non-target vegetation over existing isoxaflutole agricultural uses approved by EPA when used according to the product label. As noted in Subsection 4.2.2 – Agronomic Practices, Bayer has submitted new registration information to the EPA to change the label use restrictions for the application of isoxaflutole to soybean (Bayer, 2011c). As noted above in the No Action Alternative, current isoxaflutole labels provide use requirements to avoid herbicide drift, including spray droplet size, nozzle configurations, spray pressure, spray volume, equipment ground speed, spray boom height, ambient air temperature and humidity, wind speed and direction, and sensitive areas (see Appendix A). As previously noted, growers are required to comply with pesticide label use requirements under Federal and state law; APHIS assumes that growers and herbicide applicators apply herbicides in compliance with the label use requirements. The above noted use limitations, are expected to minimize the potential for offsite movement (spray drift and volatility), presenting minimal risk to adjacent crops (Bayer, 2011c).

The drift of dust from pesticide applications can expose people, wildlife, and the environment to pesticide residues that can cause health and environmental effects and property damage (EPA, 2009d). Concerns over the dust from isoxaflutole treated fields in dry years and the potential to pose a hazard to non-target plants has been raised during the public comment process for the development of this EA. To prevent off-site movement of soil containing isoxaflutole to non-

[30] Driftwatch is a voluntary program that allows growers to report the locations of fields in which crops sensitive to herbicides are being grown (and also identifies other types of sensitive areas), the sensitive crop information is presented on a website in a map format which can then be utilized by pesticide applicators prior to application L. Hahn, L. Theller, A. Reimer and B. Engel, "Pesticides Sensitive Crops and Habitats: Registry Implementation Results," (Washington D.C.: American Chemical Society, 2011), vol..

target areas, label directions instruct applicators not to use in areas receiving less than 15 inches of average annual precipitation unless supplemented with the equivalent in irrigation water (Appendix A). These same EPA label use restrictions are in place for current use of isoxaflutole on corn (Bayer, 2011b). APHIS assumes that growers will continue to use herbicides in accordance with the label requirements to minimize potential impacts to air associated with drift of dust.

APHIS assumes that if EPA determines any label changes are required to minimize off-site movement, growers will adapt and adopt those label use requirements as part of their best management practices. APHIS assumes that growers will continue to use the herbicides in accordance with the label requirements.

As noted in Subsection 2.1 – Agricultural Production of Soybean, glyphosate is currently widely used in American agriculture, including soybeans and crops in the soybean rotation. Bayer anticipates that growers cultivating this double herbicide resistant soybean will not eliminate glyphosate as an herbicide, but will incorporate isoxaflutole as part of a tank mix with glyphosate to control glyphosate-resistant weeds (Bayer, 2011c). The current application rates of glyphosate are not expected to change from those currently in use (Bayer, 2011c). EPA label restrictions are currently in place to minimize potential glyphosate impacts to air associated with drift (Monsanto, 2010).

Based on this information, APHIS concludes that the cultivation of FG72 soybean is not expected to adversely impact air quality.

4.3.4 Climate Change

No Action Alternative: Climate Change

Agriculture, including land-use changes associated with farming, is responsible for an estimated 6% of all human-induced GHG emissions in the United States (EPA, 2012b). Agriculture-related GHG emissions include CO_2, N_2O, and CH_4, produced through the combustion of fossil fuels to run farm equipment; the use of fertilizers; or the decomposition of agricultural waste products, including crop residues, animal wastes, and enteric emissions from livestock. N_2O emissions from agricultural soil management (primarily nitrogen-based fertilizer use) represent 68% of all U.S. N_2O emissions (EPA, 2012b).

Conservation tillage practices used in U.S. soybean production has been identified as providing climate change benefits (see e.g., (Brenner et al., 2001). Conservation tillage, discussed above in Agronomic Practices (Subsections 2.1.2 and 4.2.2) and Soil Quality (Subsections 2.2.1 and 4.3.1), in addition to providing benefits to soil quality, also has the benefit of increasing carbon sequestration in soils. Switching from conventional tillage to a no-till corn-soybean rotation in Iowa, for example, has been estimated to increase carbon sequestration by 550 kg/hectare (485 lb./acre) per year (Paustian et al., 2000; Brenner et al., 2001; Towery and Werblow, 2010).

Under the No Action Alternative, current impacts on climate change associated with soybean production would not be affected. Agronomic practices associated with soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and use of agriculture equipment would continue on soybeans grown throughout the region.

FG72 soybean use would be limited to areas APHIS has approved it for regulated releases under the No Action Alternative. Agronomic management practices and phenotypic characteristics regarding FG72 soybean are similar to those of conventional soybean, so impact from soybean varieties would be minimal. Measurable effects from these confined field releases would also be minor because of the small scale of management and acreage relative to current soybean production in the U.S.

Preferred Alternative: Climate Change

As described in Section 4.2.1, the range and area of U.S. soybean production is not likely to expand under the Preferred Alternative. As described in the Bayer petition (Bayer, 2011c) and APHIS PPRA (USDA-APHIS, 2012d), FG72 soybean requires management strategies similar to that for conventional soybean production, thus precluding changes in agricultural activities that may affect climate change, such as machine usage and tillage. Collectively, because the range, area, and agronomic practices of soybean are unlikely to change following a determination of nonregulated status of FG72 soybean, the agricultural impacts of soybean cultivation are also unlikely to change under the Preferred Alternative.

While agricultural activities may affect climate change, the converse is also true; climate change may affect agriculture. For example, climate change may result in shifts of herbivorous insects to higher latitudes. There is evidence that insect diversity and vegetative consumption intensity increase with increasing temperature at the same latitude in the fossil record (Bale et al., 2002). How climate change will affect individual species of pest insects will depend on their physiology, feeding behavior, and overwintering strategies (Bale et al., 2002). In cases where climate change favors the expansion of the range of soybean pests, additional soybean acres may be treated with insecticides. FG72 soybean is not any more susceptible to insect herbivory than conventional soybean varieties (USDA-APHIS, 2012d), so change in insect pressure resulting from climate change is likely to impact FG72 soybean just as it would conventional soybean.

4.4 Biological Resources

4.4.1 Animal Communities

No Action Alternative: Animal Communities

Soybean production fields may be host to many animal and insect species. Mammals and birds may use soybean fields and the surrounding vegetation for food and habitat throughout the year. Invertebrates can feed on soybean plants or prey upon other insects living on soybean plants as well as in the vegetation surrounding soybean fields.

Animal communities associated with soybean cultivation will continue to be exposed to GE and non-GE soybean in various aspects of agricultural production practices and agronomic inputs, including various pesticides. These practices include tillage, cultivation, pesticide and fertilizer applications, and the use of agricultural equipment. The animal communities will continue to be exposed to the expressed proteins in the various commercialized GE crop plants.

Agricultural production of existing nonregulated herbicide-resistant GE and non-GE soybean continues to utilize those EPA-registered pesticides listed in Tables 3, 4, and 5 for pest management. The environmental risks of pesticide use on wildlife and wildlife habitat are assessed by EPA in the pesticide registration process and are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. EPA's process ensures that each registered pesticide continues to meet the highest standards of safety to protect human health and the environment.

Under the No Action Alternative, conventional soybean production would continue while FG72 soybean remains a regulated article. Potential impacts to animal communities associated with soybean cultivation are not expected to change in the No-Action Alternative.

Preferred Alternative: Animal Communities

Under the Preferred Alternative, potential impacts to mammals, birds, invertebrates, reptiles, amphibians, fish and benthic invertebrates are not anticipated to be substantially different compared to the No Action Alternative.

Potential impacts to animal communities arise from any changes in agronomic inputs associated with the crop modification and direct exposure to the GE crop and its products, and corresponding indirect impacts associated with, in this case, herbicide use changes associated with the herbicide resistance trait in FG72 soybean.

As described in Subsection 4.2, Bayer has presented the results of field trials which demonstrate that FG72 soybean does not require any changes to agronomic inputs when compared with conventional soybean, with the exception of the ability to use isoxaflutole (Bayer, 2011c; USDA-APHIS, 2012d). Land use and agricultural production of soybean under the Preferred Alternative is likely to continue as currently practiced. Consequently, any impact to animal communities as a result of soybean production practices under the Preferred Alternative is likely to be similar to the No Action Alternative.

Consumption of FG72 soybean is unlikely to substantially affect non-target organisms, such as animals, birds, or insects. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, demonstrating that it is not likely to have any significant impact on animal health (USDA-APHIS, 1997; CFIA, 1998; FSANZ, 2001; SCF, 2002). Though HPPD W336 has not previously been evaluated, there is no reason to suspect it would present a risk to non-target organisms. HPPD proteins are ubiquitous in the environment and are not novel. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c). Additionally, compositional analysis of FG72 soybean proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations revealed no substantial differences between it and conventional soybean varieties (Bayer, 2011c).

Non-target organisms may be exposed to glyphosate and isoxaflutole under the Preferred Alternative. The majority of U.S. soybean acreage is already subject to glyphosate application (USDA-NASS, 2013a); consequently, exposure to glyphosate through the cultivation of FG72 soybean is not likely to increase non-target organism exposure to glyphosate. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012c), exposure to glyphosate by non-target organisms is expected to be similar to the No Action Alternative. The potential impact of isoxaflutole on non-target organisms has been evaluated by the EPA (EPA, 2011b; EPA, 2011h). In summary, following three separate ecological risk assessments, EPA concluded that the level of concern for acute and chronic risks for birds, mammals, and fish was not exceeded as a result of isoxaflutole application (Tables C3-C4, Appendix C). On an acute contact and oral basis, isoxaflutole was determined to be practically non-toxic to honey bees (*Apis mellifera*) (Table 23) (EPA, 2011h). Mysid shrimp (*Mysidopsis bahia*), an estuarine invertebrate species, was found to be highly sensitive to isoxaflutole (LC_{50} = 0.018) (Table 24) (DATCP, 2002); however, given the rapid decay of parent isoxaflutole to diketonitrile and the decreased sensitivity of *M. bahia* to diketonitrile (LC_{50} = 3.6) (EPA, 2011h), this may be less of an issue in field conditions. As a result of these conclusions, it is unlikely that isoxaflutole would pose a risk to animal communities under the Preferred Alternative.

Table 23. Summary of the most sensitive endpoints from submitted terrestrial toxicity studies for isoxaflutole.

Taxa represented	Species (common name)	Toxicity value	Comments
Birds, terrestrial-phase amphibians and reptiles	Bobwhite quail (*Colinus virginianus*)	LD_{50} > 2150 mg/kg-bw	No observed mortalities at highest treatment level.
		LD_{50} > 4255 mg/kg-food	
	Mallard duck (*Anas platyrhynchos*)	LD_{50} > 2150 mg/kg-bw	
		LD_{50} > 4255 mg/kg-food	
Terrestrial mammals	Laboratory rat (*Rattus norvegicus*)	LD_{50} > 5000 mg/kg-bw	Acute inhalation LC50 > 5.23 mg/L.
		NOAEC = 17.4 mg a.i./kg-food	Values based on exposure to males; LOAEC = 414 mg/kg-food based on decreased body weight in parents and offspring.
Terrestrial invertebrates	Honey bee (*Apis mellifera*)	LD_{50} > 100 mg/kg-bw	No observed mortalities at highest treatment level. Oral LD_{50} > 168.7 ug/bee.

Source: EPA(EPA, 2011h).

Table 24. Summary of the most sensitive endpoints for submitted aquatic toxicity studies for isoxaflutole.

Taxa represented	Species (common name)	Toxicity value (mg a.i./L)	Comments
Freshwater fish and aquatic-phase	Rainbow trout (*Oncorhynchus mykiss*)	96-hr LC_{50} > 1.7	No observed mortalities at highest treatment level. 1.7 ppm represents maximum water solubility obtainable under test conditions.

Taxa represented	Species (common name)	Toxicity value (mg a.i./L)	Comments
amphibians		NOAEC = 0.096	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for rainbow trout.
Freshwater invertebrates	Water flea (*Daphnia magna*)	48-hr LC_{50} > 1.5	No observed immobility at highest treatment level. 1.5 ppm represents maximum water solubility obtainable under test conditions.
		NOAEC = 0.084	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for water flea.
Estuarine/ Marine fish	Sheepshead minnow (*Cyprinodon variegatus*)	96-hr LC_{50} > 6.4	No observed immobility at highest treatment level. 6.4 ppm represents maximum water solubility obtainable under test conditions.
		NOAEC = 0.36	No toxicity data are available for this taxa. NOAEC derived using ACR for mysid shrimp (17.8) and acute toxicity value for sheepshead minnow.
Estuarine/ Marine invertebrates	Mysid shrimp (*Mysidopsis bahia*)	96-hr LC_{50} > 0.0178	Slope = 2.9.
		NOAEC = 0.001	LOAEC = 0.0019 based on effects to survival.

Source: EPA(EPA, 2011h).

4.4.2 Plant Communities

<u>No Action Alternative: Plant Communities</u>

Plant communities within agroecosystems are generally less diverse than the plant communities that border crop fields. This lack of diversity is attributable to ecological selection that is imposed by crop production practices such as tillage and herbicide use (Owen, 2008). The plant communities that inhabit crop production fields are represented by plants (including weeds) that are able to adapt and thrive in an environment that is directed specifically to the production of crops, such as soybean. In crop production systems, the plant community is controlled using a number of tactics to maximize the production of food, fiber, and fuel; however, herbicides are the most common and accepted tactic to manage plant communities within agroecosystems (Gianessi and Reigner, 2007).

The landscape surrounding a soybean field may be bordered by a number of vegetative communities, including other soybean (or any other crop) fields, woodland, rangelands, and/or pasture/grassland areas. These plant communities represent natural or managed plant buffers for the control of soil and wind erosion and also serve as habitats for a variety of transient and non-transient wildlife species.

One of the highest priorities in soybean production is weed management (Hoeft et al., 2000). Weeds compete with soybean for water, soil nutrients and light, and may ultimately reduce yield. Growers use cultural methods, cultivation and herbicides to control crop competitors, and, depending on the strategies chosen, different herbaceous annuals, perennials, or even woody species can become established (Hoeft et al., 2000). Weeds present during an entire growing season can result in soybean yield losses ranging from 12 to 80 percent (Barrentine, 1989).

Under the No Action Alternative, FG72 soybean would remain under APHIS regulation. Soybean production would likely continue as it does today, with the majority of acres being planted with GE herbicide-resistant soybean. Weed species that typically inhabit soybean production systems will continue to be managed through the use of mechanical, cultural, and chemical control methods, including the use of glyphosate and other registered herbicides. The majority of U.S. soybean acres will continue to be subject to herbicide application.

As discussed in Subsection 4.3.1 – Soil Quality, and 4.3.3 – Air Quality, herbicide runoff and spray drift have the potential to impact non-target plants growing near fields where the herbicides are used. As noted in Subsection 1.1, Coordinated Framework Review and Regulatory Review, the EPA has exclusive jurisdiction to consider the environmental risks of pesticide use under FIFRA; the EPA evaluates these risks, including risks to non-target plants in the pesticide registration process (EPA, 2011f). As discussed in Subsection 4.3.3 – Air Quality, for example, the current pesticide labels for both glyphosate and isoxaflutole include use restrictions and guidelines on spray droplet size, wind speeds, ambient temperature, and specific equipment requirements regarding boom length and height above the canopy imposed by the EPA to minimize impacts to non-target plants (Monsanto, 2010; Bayer, 2011b). APHIS assumes that growers will adhere to these pesticide label use restrictions when making pesticide applications.

Growers will continue to respond to the development of glyphosate- and other herbicide-resistant weeds by diversifying weed management strategies (Norsworthy et al., 2012). This includes utilizing herbicides with different MOAs, using tank mixes, increasing the frequency of glyphosate applications, and returning to tillage and other cultivation techniques to physically control these species when herbicides prove to be ineffective (Norsworthy et al., 2012; Shaw et al., 2012).

Weed scientists have recommended the use of multiple herbicide MOAs in agricultural crop production to provide broad spectrum weed control and to delay the evolution of weed resistance or to control weeds that are already resistant to a particular herbicide or herbicide MOA. Recent recommendations for the use of multiple MOAs in mixtures, sequences and/or rotation is based on studies that have shown resistance can be postponed, contained and managed through good management practices (Beckie and Reboud, 2009; Neve et al., 2011; HRAC, 2013). Simultaneously using two herbicides with different MOAs reduces the probability of weeds developing resistance to either or both herbicides (Powles et al., 1996; Beckie and Reboud, 2009). These practices are already a part of soybean crop management. Recent market research has demonstrated that growers are adopting weed management practices that utilize multiple herbicide MOAs in Roundup Ready® soybeans (Givens et al., 2009; Hurley et al., 2009; Prince et al., 2011). These practices are expected to continue under the No Action Alternative. Moreover, the continued increase in the application of pre- and post-emergent herbicides as part of diverse weed management strategy is expected to continue under the No Action Alternative.

Preferred Alternative: Plant Communities

Under the Preferred Alternative, FG72 soybean is not expected to affect plant communities due to toxicity or allergenicity of the transgene proteins. Both introduced proteins, 2mEPSPS and HPPD W336, are not derived from organisms that are known for pathogenic or toxic effects on plants; these traits themselves are effectively benign in the environment (Bayer, 2011c). There are no compatible wild relatives of soybean in the U.S. (OECD, 2010), so there will be no impact on the wild genetic resources of soybean following a determination a nonregulated status of FG72 soybean. Furthermore, FG72 soybean does not display or possess any weedy characteristics, and thus, is not expected to behave as a weed (USDA-APHIS, 2012d).

FG72 soybean will permit the continued use of glyphosate on soybean, as described in Section 4.2.2. Thus, any impact of glyphosate use on the plant community will be the same as the No Action Alternative. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012b), the impacts on the plant community in soybean from glyphosate is expected to be similar to the No Action Alternative.

As described in Section 4.2.2, FG72 soybean may also facilitate the increased use of isoxaflutole in U.S. soybean production. The use of isoxaflutole in the cultivation of FG72 soybean represents a change to vegetation management in and adjacent to soybean fields when compared with the No Action Alternative. Isoxaflutole, through its degradation to diketonitrile, functions as a nonselective herbicide. Therefore, both non-target plant and weed species may experience high levels of toxicity following exposure to isoxaflutole. Possible routes of exposure include direct exposure in the agricultural field and runoff. Soybean weed species are the most likely to be exposed to isoxaflutole through direct application. As a nonselective herbicide, isoxaflutole can be expected to control a wide variety soybean weed species (Table 25). Direct exposure of weeds to isoxaflutole under the Preferred Alternative is not anticipated to be substantially different than direct exposure of weeds to alternative herbicides under the No Action Alternative, as isoxaflutole represents yet another herbicide in a growing diversity of herbicides utilized in soybean production (Section 4.2.2). The application of herbicides with multiple MOAs is expected to continue under the Preferred Alternative, as growers incorporate the use of multiple herbicide MOAs in agricultural crop production to provide broad spectrum weed control and to delay the evolution of weed resistance or to control weeds that are already resistant to a particular herbicide or herbicide MOA (Beckie and Reboud, 2009; Neve et al., 2011; Norsworthy et al., 2012).

Table 25. Control of 10 most common weeds of soybeans by isoxaflutole (Balance® Pro). C = controlled; S = suppression; and N = not controlled or suppressed.

Midwest		Southeast		Eastern Coastal	
Weed	**Isoxaflutole efficiency**	**Weed**	**Isoxaflutole efficiency**	**Weed**	**Isoxaflutole efficiency**
Common waterhemp*	N	Redroot pigweed	C	Redroot pigweed	C
Velvetleaf	C	Morning glory	C	Lambsquarters	C
Foxtail	C	Johnson grass	C	Ragweed	C
Redroot	C	Palmer	C	Foxtail	C

pigweed		amaranth			
Lambsquarters	C	Sicklepod	-	Johnson grass	C
Marestail	C	Marestail	C	Cocklebur	N
Cocklebur	N	Barnyard Grass	C	Marestail	C
Giant ragweed	S	Cocklebur	N	Fall panicum	C
Yellow foxtail	C	Grasses, All	C	Morning glory	C
Giant foxtail	C	Broadleaf signalgrass	C	Giant ragweed	S

Adapted from DATCP (2002) (Heap, 2013).
Notes: Midwest Soybean Production States are considered as IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, OK, SD, and WI.
Southeast Soybean Production States are considered as AL, AR, FL, GA, LA, MS, NC, SC, TN, and TX.
Eastern Coastal soybean production states are considered as: DE, MD, NJ, NY, PA, VA, and WV.
* Resistant biotypes have been identified in Iowa.

As described in Section 4.3.2, runoff may pose an environmental risk to non-target plants (EPA, 2011g). However, as a consequence of its registration, EPA has determined that there is no unreasonable environmental risk if the end user adheres to the label use restrictions when applying isoxaflutole herbicide formulations. EPA label directions include application restrictions plus requirement for a certified applicator to minimize effects on nearby environments (Bayer, 2011a; Bayer, 2011b). Violators of the regulations are liable for all negative consequences of their actions. This serves as an added incentive to farmers who use restricted use pesticides, so they are more likely to carefully follow its label restrictions. Given that the leaching potential of isoxaflutole is not substantially higher than many currently-registered soybean herbicides (Table 22), it is unlikely that isoxaflutole poses any more of a risk to non-target plants than the herbicides that would otherwise be utilized under the No Action Alternative. Isoxaflutole is currently undergoing a registration review by EPA (EPA, 2011c). If EPA determines that additional restrictions beyond current restrictions (Appendix A) on isoxaflutole use are required to mitigate environmental risk to non-target plant communities, then it is expected that EPA would amend isoxaflutole use labels accordingly.

As discussed in Subsection 4.3.1 – Soil Quality and 4.3.3 – Air Quality, EPA acknowledges that isoxaflutole, like most herbicides, may impact non-target plants from off-target drift and runoff (EPA, 1997). The EPA labels for Balance® Pro herbicides, the common brands of isoxaflutole used on corn, include measures to minimize herbicide drift (including specific directions and restrictions for nozzle height, spray pressure and wind speed) and runoff (including directions and restrictions for use in and around water) (Bayer, 2011b). These label use restrictions are already in place and implemented by growers and commercial applicators using isoxaflutole on corn, and are not expected to change with the cultivation of FG72 soybean. APHIS assumes that any application of this herbicide is conducted in accordance with these label restrictions.

Weed populations can change in response to multiple agricultural management decisions, including those related to herbicide application. At present, nine glyphosate-resistant weeds have been identified in soybean fields (Figure 4), inhabiting approximately two million acres of farmland in the U.S. (Hubbard, 2008). As described in Section 4.2.2, FG72 soybean may facilitate the use of isoxaflutole in U.S. soybean production. Following a determination of nonregulated status of FG72 soybean, isoxaflutole application may be utilized to control glyphosate-resistant weeds in U.S. soybean fields. Possessing an alternative MOA, isoxaflutole is expected to control glyphosate-resistant weeds. Of the nine glyphosate-resistant weeds found in U.S. soybean fields, horseweed, Palmer amaranth, common ragweed, goosegrass, kochia, and spiny amaranth are controlled by isoxaflutole (Table 26). Control of the remaining glyphosate-resistant weeds potentially found in soybean fields, such as giant ragweed, ridged ryegrass, or Italian ryegrass, may be controlled by alternative herbicide use alone or in conjunction with isoxaflutole.

Table 26. Control of glyphosate-resistant weeds found in soybean by isoxaflutole (Balance® Pro). C = controlled; S = suppression; and N = not controlled or suppressed.

Midwest		**Southeast**		**Eastern Coastal**	
Species	**Isoxaflutole Efficiency**	**Species**	**Isoxaflutole efficiency**	**Species**	**Isoxaflutole efficiency**
Common ragweed (*Ambrosia artemisiifolia*)	C	Common ragweed (*Ambrosia artemisiifolia*)	C	Horseweed (*Conyza canadensis*)	C
Common waterhemp (*Amaranthus rudis*)	N	Common waterhemp (*Amaranthus rudis*)	C	Palmer amaranth (*Amaranthus palmeri*)	C
Giant ragweed (*Ambrosia trifida*)	S	Giant ragweed (*Ambrosia trifida*)	S		
Horseweed (*Conyza canadensis*)	C	Goosegrass (*Eleusine indica*)	C		
Kochia (*Kochia scoparia*)	C	Horseweed (*Conyza canadensis*)	C		
Palmer amaranth (*Amaranthus palmeri*)	C	Italian ryegrass (*Lolium multiflorum*)	N		
Rigid ryegrass (*Lolium rigidum*)	N	Palmer amaranth (*Amaranthus palmeri*)	C		
		Rigid ryegrass (*Lolium rigidum*)	N		
		Spiny amaranth (*Amaranthus spinosus*)	C		

Source: Bayer Proprietary Third Party Data Source and Adapted from DATCP (2002).
Notes: Midwest Soybean Production States are considered as IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, OK, SD, and WI
Southeast Soybean Production States are considered as AL, AR, FL, GA, LA, MS, NC, SC, TN, and TX.
Eastern Coastal soybean production states are considered as: DE, MD, NJ, NY, PA, VA, and WV.

Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska corn fields were reported to be resistant to 4-HPPD inhibitors (Heap, 2011). While three of these biotypes were resistant to the triketone family of 4-HPPD inhibitors, cross-family resistance to isoxaflutole may be possible. One example of this was found in 2011 in a common waterhemp biotype from Iowa that displayed cross-family resistance to triketone-based 4-HPPD inhibitors as well as isoxaflutole (Heap, 2011). The conditions leading to the advent of at least one of these reported cases is not likely to be common in FG72 soybean fields. In the Illinois biotype found in 2009, an absence of crop and herbicide rotation in the corn seed production field contributed to the development of 4-HPPD resistance (Hausman et al., 2011). Unlike seed corn production fields, however, the majority of soybean production fields are rotated with another crop (USDA-ERS, 2011b). FG72 soybean fields are not anticipated to be any different. Rotating FG72 soybean with corn would increase the likelihood of using isoxaflutole in consecutive years, which could potentially select for isoxaflutole resistant weeds. However, since isoxaflutole is limited to use on corn and soybean as registered by the EPA (Bayer, 2011a; Bayer, 2011b), the development of isoxaflutole resistant weeds would be unlikely to affect other cropping systems since these growers would be using herbicides other than isoxaflutole on their crops.

Based on these findings, APHIS has determined that an approval of the petition for nonregulation of FG72 soybean will not impact plant communities.

4.4.3 Gene Flow and Weediness

No Action Alternative: Gene Flow and Weediness

Soybean is a self-pollinated species, propagated by seed (OECD, 2010). Pollination typically takes place on the day the flower opens. The soybean stigma is receptive to pollen approximately 24 hours before anthesis and remains receptive for 48 hours after anthesis. Anthesis normally occurs in late morning, depending on the environmental conditions. The pollen usually remains viable for two to four hours, and no viable pollen can be detected by late afternoon. Natural or artificial cross-pollination can only take place during the short time when the pollen is viable. As a result, soybean is considered to be a highly self-pollinated species, with cross-pollination to adjacent plants of other soybean varieties occurring at a very low frequency (0 to 6.3 percent) (Caviness; Ray et al., 2003; Yoshimura et al., 2006; USDA-APHIS, 2011).

Under the No Action Alternative, conventional soybean varieties, including GE soybean varieties no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act, will continue to be grown commercially while FG72 soybean will remain a regulated article. Soybean cultivation practices are expected to remain the same. Gene flow from current commercially available GE cultivars to non-GE soybean cultivars is expected to remain unchanged from the current conditions.

Preferred Alternative: Gene Flow and Weediness

There are no compatible relatives of soybean in the U.S. Thus, gene flow is only possible between domesticated soybean plants (OECD, 2010). Soybean is predominantly a self-pollinated species (OECD, 2000), yet a small amount of outcrossing does occur. However, current cultivation practices to prevent out-crossing have been deemed sufficient to prevent unwanted gene flow. For soybean, the Association of Official Seed Certifying Agencies (AOSCA) mandates a zero isolation distance: “Fields of soybeans shall be separated from any other variety or uncertified seed of the same variety by a distance adequate to prevent mechanical mixture.”

FG72 soybean, compared to its non-transgenic parent variety (Jack), did not exhibit any changes in reproductive characteristics that would increase likelihood of gene flow, such as fecundity, seed dispersal, increased persistence, or pollen viability/germination (Bayer, 2011c; USDA-APHIS, 2012d). Thus, under the Preferred Alternative, the likelihood of gene flow from FG72 soybean to other soybean varieties is not substantially different than between current soybean varieties.

FG72 soybean is not likely to be weedy. Soybean is not identified as a weed in the U.S. Phenotypic and agronomic characteristics of FG72 soybean were evaluated in a comparative manner to assess plant pest potential (OECD, 1993). These assessments included 17 plant growth and development characteristics: early stand count, plant vigor, days to flowering, flower color, leaf shape, health rating at stage V4-5, health rating at stage R1, health rating of mature plants, pubescence color, pod color, hilum color, canopy, days to maturity, yield in bushels per acre, lodging, final stand count and pod shatter (Bayer, 2011c). Results of these evaluations indicate that there is no fundamental difference between FG72 soybean and conventional soybean for traits associated with weediness. Collectively, these findings support the conclusion that FG72 soybean is no more likely to be a weed compared to conventional soybean (USDA-APHIS, 2012d).

4.4.4 Microorganisms

No Action Alternative: Microorganisms

In particular, the soil microbial community is an integral ecosystem component that may provide and sustain critical ecological processes. Nutrient cycling, establishing soil structure contributing to plant growth, and metabolism of deleterious components are all dependent on the microbial constituents. The health and growth of these microbes may be influenced by many processes and conditions in agriculture, such as the crop cultivated or the tillage method utilized (Steenwerth et al., 2002).

Under the No Action AlternativeFG72 soybean will continue to be regulated by APHIS. As discussed in Subsection 4.2.2 – Agronomic Practices, soybean cultivation practices are expected to remain as currently practiced. Growers will continue to have access to existing GE soybean varieties (including herbicide-resistant and modified functional traits) as well as non-GE varieties. Growers will continue to manage their crops, including implementing numerous management strategies to control pests and weeds. As discussed in Subsection 4.2.2 – Agronomic Practices, these current practices include the use of a wide range of herbicides for the control of certain weeds in soybean. Under the No Action Alternative, soil microorganisms will continue being exposed to GE soybean varieties, their introduced proteins, and the agronomic practices currently used to cultivate these GE soybean varieties.

The cultivation of GE crops has not been demonstrated to present environmental risks to soil microbial populations (Vencill et al., 2012). The diversity of microbial populations may be affected by these crops, but effects reported to date have been transient and minor (Dunfield and Germida, 2004; Vencill et al., 2012).

The microorganisms in the rhizosphere have the potential to be impacted by applications of herbicides. As noted in Subsection 2.1.2 and 4.2.2 – Agronomic Practices, a wide range of herbicides with multiple MOAs are already applied to soybeans and other crops in soybean rotation. These herbicide applications, and the corresponding influences to the rhizosphere, are unlikely to change in the No Action Alternative.

Soybeans have a symbiotic relationship with *Bradyrhizobium japonicum*, a plant-associated nitrogen-fixing bacterium. This relationship, and the growers' need to inoculate soybean seeds with this bacterium, is not likely to change under the No Action Alternative.

Under the No Action Alternative, soybean cultivation practices would continue as currently practiced. Microbes in the field would continue to be exposed to common agronomic practices, glyphosate, and other pesticides applied to soybean. Impacts to the soil microbial community are not likely to change under the No Action Alternative.

<u>Preferred Alternative: Microorganisms</u>

Under the Preferred Alternative, soil microorganisms are unlikely to be substantially affected by approval of a petition for nonregulated status of FG72 soybean compared to the No Action Alternative. The main factors influencing soil microbial populations include soil type (texture, structure, organic matter, aggregate stability, pH, and nutrient content), plant type (providers of specific carbon and energy sources into the soil), and agricultural management practices (crop rotation, tillage, herbicide and fertilizer application, and irrigation) (Steenwerth et al., 2002; Garbeva et al., 2004).

As discussed in Subsection 4.2 – Agricultural Production of Soybean, Bayer has presented evidence from field trials that FG72 soybean requires similar cultivation practices as commercialized soybean varieties, suggesting that a determination of nonregulated status is unlikely to substantially change current soybean production practices. In particular, tillage patterns have been identified as an important determinant of soil microbial community and structure (Lupwayi et al., 1998; Kladivko, 2001). Consequently, under the Preferred Alternative, FG72 soybean is unlikely to substantially affect microbial community and structure because it represents another herbicide-resistant soybean variety that may enable conservation tillage strategies widely practiced in U.S. soybean production (NRC, 2010a). Further support is evident from the decomposition of FG72 soybean plant material in the field following the implementation of conservation tillage (CTIC, 2008). It is unlikely to substantially affect the soil microbial community because FG72 soybean does not substantially differ from conventional soybean in compositional factors, including proximate and fiber components, amino and fatty acids, and relevant soybean anti-nutrients and isoflavones (USDA-APHIS, 2012d).

Field observations were conducted to assess potential agronomic differences between FG72 soybean and conventional soybean in 2003 and 2008 and at a total of 15 planting sites (Bayer, 2011c). The disease analysis included observation of a wide range of bacterial and fungal pathogens, including downy mildew (*Peronospora manshurica*); bacterial blight (*Pseudomonas syringae* pv. *Glycinea*); Cercospora leaf blight (*Cercospora kikuchii*); brown spot (*Septoria glycines*); frogeye leafspot (*Cercospora sojina*); powdery mildew (*Microsphaera diffusa*); and sudden death syndrome (*Fusarium virguliforme*). No differences in disease susceptibility were observed between FG72 and conventional soybean, suggesting that the two introduced traits did not alter soybean interactions with microorganisms in the field (USDA-APHIS, 2012d).

Cultivation of FG72 soybean and the associated application of glyphosate and isoxaflutole is not expected to impact soil microorganisms. Isoxaflutole is currently applied to corn. Isoxaflutole was first registered in the U.S. in 1998; the most recent isoxaflutole ecological risk assessment was conducted in April 2010 for use on soybeans (EPA, 2011b). It is currently under reregistration review, which began in June 2011 and is scheduled for completion in 2017 (EPA, 2011b). Impacts to soil microorganisms have not been raised as a concern. The European Commission conducted a test of the potential impacts of isoxaflutole on soil microorganisms by evaluating soil carbon respiration and nitrogen transformation in soils treated with isoxaflutole (European Commission, 2003). No long term effects on soil microorganisms were identified (European Commission, 2003). This is consistent with the EPA's finding that isoxaflutole is readily degraded in soil by soil microorganisms (EPA, 1998; EPA, 2011h).

As noted in subsection 2.1.2, glyphosate was applied to 98% of the soybean acreage in the United States (USDA-NASS, 2013b; USDA-NASS, 2013a). The potential impacts of the application of glyphosate on soil microorganisms have been considered by the EPA in the current registration analysis, and summarized by APHIS in previous environmental documents for petitions for nonregulated status (EPA, 1993; USDA-APHIS, 2012c). As discussed in Subsection 4.2 – Agricultural Production, approval of a determination of nonregulation of FG72 soybean is unlikely to affect the application of glyphosate to soybean.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of FG72 soybean will not impact soil microorganisms.

4.4.5 Biodiversity

No Action Alternative: Biodiversity

As discussed in Subsection 2.3.5 – Biodiversity, currently commercialized GE crops have reduced the impacts of agriculture on biodiversity through current use of conservation tillage practices, reduction of insecticide use, the use of more environmentally benign herbicides, and increasing yields to alleviate pressure to convert additional land into agricultural use (Young and Ritz, 2000; Jasinski et al., 2003; Carpenter, 2011).

Biological diversity, or the variation in species or life forms in an area, is highly managed in agricultural systems. Farmers typically plant crops that are genetically adapted to grow well in a specific area of cultivation and have been bred for a specific market. In conventional agriculture, farmers want to encourage high yields from their crop, and will intensively manage plant and animal communities through chemical and cultural controls to protect the crop from damage. Therefore, the biological diversity in agricultural systems (the agro-ecosystem) is highly managed and may be lower than in the surrounding habitats.

Under the No Action Alternative, FG72 soybean would continue to be a regulated article. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would continue to have access to conventional soybean varieties, including GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Agronomic practices associated with conventional soybean production such as tillage, cultivation, irrigation, pesticide application, fertilizer applications and agriculture equipment would continue unchanged. Animal and plant species that typically inhabit soybean production fields will continue to be affected by currently utilized management plans and systems, which include the use of mechanical, cultural, and chemical control methods. The consequences of current agronomic practices associated with soybean production, both traditional and GE varieties, on the biodiversity of plant and animal communities is unlikely to be altered.

The use of broad spectrum insecticides and herbicides is one of the most severe constraints for biological diversity in crops (Carpenter, 2011). Tillage, seed bed preparation, planting of a monoculture crop, pesticide use, fertilizer use, and harvest may all limit the diversity of plants and animals (Jasinski et al., 2003; Lovett et al., 2003; Towery and Werblow, 2010). Herbicide use in agricultural fields is likely to indirectly impact biodiversity by decreasing weed species present in the field and those insects, birds and mammals that utilize these weeds, although distinguishing direct and indirect impacts of agronomic practices is difficult (see e.g., (Marshall et al., 2002).

Although herbicide use potentially affects biodiversity, the application of pesticides in accordance with EPA registered label uses and careful management of chemical spray drift minimizes the potential biodiversity impacts from their use. The EPA has considered this in its registration and has established label use restrictions to minimize glyphosate and isoxaflutole drift (see (Monsanto, 2010) and (Bayer, 2011b). Glyphosate was found by the EPA to be no more than slightly toxic to birds, moderately toxic to practically nontoxic to fish, and practically nontoxic to aquatic invertebrates and honeybees (EPA, 1993). EPA concluded that the level of concern for acute and chronic risks for birds, mammals, and fish was not exceeded as a result of isoxaflutole application (EPA, 2011b). APHIS expects that growers and pesticide applicators are implementing necessary and appropriate label mitigation measures and management strategies to avoid herbicide drift and non-target impacts.

Conservation tillage practices, as described in Subsection 4.2.2 – Agronomic Practices, can have a positive impact on wildlife, including beneficial arthropods (Altieri, 1999; Landis et al., 2005; Towery and Werblow, 2010). Conservation tillage benefits to biodiversity arise from decreased soil erosion and corresponding improved surface water quality; retention of vegetative cover and crop residues that serve as a food source; and increased populations of invertebrates which can serve as food sources to other organisms (Landis et al., 2005; Sharpe, 2010). To the extent growers are able to continue to practice conservation tillage by the adoption of herbicide-resistant soybean varieties, biodiversity will recognize a corresponding benefit.

Impacts to biodiversity associated with agronomic practices in cultivating soybean are not expected to change under the No Action Alternative.

<u>Preferred Alternative: Biodiversity</u>

Although soybean production fields are cultivated as plant monocultures to optimize yield, the adjacent landscape may harbor a wide variety of plants and animals. Broad spectrum herbicide application has the potential to impact off-site plant communities. Under the Preferred Alternative, cultivation, management, and land-use decisions related to FG72 soybean are not likely to be substantially different from conventional soybean varieties. Therefore, the four primary determinants of biodiversity in an agroecosystem (1: Diversity of vegetation within and around the agroecosystem; 2: Permanence of various crops within the system; 3: Intensity of management, including selection and use of insecticides and herbicides; and 4: Extent of isolation of the agroecosystem from natural vegetation) (Altieri, 1999) are likely to remain unchanged under the Preferred Alternative.

As noted in Subsection 4.4.1 – Animal Communities, Bayer has presented compositional data comparing the phenotypic, morphological and compositional characteristics of FG72 soybean with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Bayer, 2011c). No biologically meaningful differences were identified between FG72 soybean and other varieties.

As discussed in Subsection 4.2 – Agricultural Production of Soybean, FG72 soybean does not require different agricultural practices or agronomic inputs for its cultivation when compared to currently available soybean varieties. Agricultural fields are currently managed to be weed free, and in the United States, 98% of soybean acreage was treated with an herbicide in 2012 (USDA-NASS, 2007a; USDA-NASS, 2013a). These herbicide use trends are not likely to change under the Preferred Alternative.

The benefits of conservation tillage practices, as described above in the No Action Alternative, will continue to be realized, and have the potential to be enhanced under this Alternative. As discussed in Subsection 4.2 – Agronomic Practices, growers cultivating FG72 soybean and using glyphosate and isoxaflutole in accordance with Bayer's recommended practices should expect better control of certain hard to control weeds. This level of control is expected to result in the minimization and avoidance of conventional tillage as a method of weed control. This practice results in continued adoption of conservation tillage and the corresponding benefits to biodiversity.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of FG72 soybean does not impact biodiversity.

4.5 Public Health

4.5.1 Human Health

<u>No Action Alternative: Human Health</u>

Under the No Action Alternative, FG72 soybean remains a regulated article. Under the No Action Alternative, human exposure to existing GE and non-GE soybean varieties and their products would not change. Grower and consumer exposure to FG72 soybean is limited to those individuals involved in the cultivation under regulated conditions.

Human exposure to conventional soybean, both GE and non-GE, does not change from the current status. This exposure includes exposure to incorporated genes and expressed proteins in many different soybean varieties as well as exposure to herbicides used on soybean. As noted in Subsection 4.2.2 – Agronomic Practices, many different herbicides are currently used on soybean, including glyphosate. These management practices, and the associated human health effects, are not likely to change under this Alternative.

Human exposure to soybean crops and products, and the agronomic inputs associated with their production, are unchanged from the current condition.

Preferred Alternative: Human Health

Human health concerns associated with a determination of nonregulated status of FG72 soybean relate to direct exposure to the modified crop and the incorporated gene/protein from consumption of GE soybean products, and potential indirect exposure associated with changes in herbicide use.

FG72 soybean contains two introduced proteins, 2mEPSPS and HPPD W336. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, thus demonstrating that it is not likely to have any significant impact on human health (USDA-APHIS, 1997; CFIA, 1998; FSANZ, 2001; SCF, 2002). HPPD W336 is currently being analyzed by several regulatory agencies (CFIA, 2011; EFSA, 2011a; FSANZ, 2011b). However, there is no evidence to suggest that HPPD W336 would be detrimental to general human health. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c). HPPD W336 is derived from *P. fluorescens*, a ubiquitous, soil-borne bacterium with a history of safe use (Maurhofer et al., 1994; Sanger, 2012). While *P. fluorescens* may occur as an opportunistic pathogen in humans, this is generally limited to immune-compromised patients (McKellar, 1982; Wong et al., 2011).

A comparison of FG72 soybean with conventional soybean varieties reveals compositional equivalence. Analysis of FG72 soybean proximate and fiber components (moisture, protein, fat, ash, carbohydrates, ADF, and NDF), amino acids, fatty acid content (C16:0; C18:0; C20:0; C22:0; C24:0; C18:1; C20:1; C18:2; and C18:3), antinutrients (phytic acid, raffinose, stachyose, letchtin, and trypsin inhibitor), and isoflavones (daidzin, genistin, glycitin, daidzein, genistein, and glycitein) demonstrated that FG72 soybean is not compositionally different from currently available soybean varieties (Bayer, 2011c; USDA-APHIS, 2012d). The characterization of soybean seed allergens also indicates that there are no substantial increases between FG72 and conventional soybean (Rouquié et al., 2010).

Food derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 5, 2009. The FDA completed its consultation and as of August 7, 2012 has no further questions (FDA, 2012a).

The general public may come into contact with glyphosate and isoxaflutole used in the cultivation of FG72 soybean. Based on information provided in existing APHIS EAs (USDA-APHIS, 2012b), the potential human health risks associated with glyphosate use is expected to be similar to the No Action Alternative. Members of the general public are unlikely to come into direct exposure with isoxaflutole as a result of application. As a restricted-use pesticide, isoxaflutole is not registered for residential use and may only be applied by certified applicators or under the direct supervision of a certified applicator, thus mitigating potential exposure to isoxaflutole prior to harvest (EPA, 2011c; EPA, 2012f). Furthermore, EPA has included use restrictions on the isoxaflutole label to mitigate potential exposure to isoxaflutole (Appendix A). EPA recently established combined tolerances for isoxaflutole and diketonitrile on soybean and aspirated soybean grain fractions following a human health risk assessment (Appendix A) (EPA, 2011e). As a result of this human health risk assessment, EPA classified isoxaflutole as "likely to be a human carcinogen" however, the carcinogenic risk is estimated to be below EPA's established level of concern for life-time cancer risk (EPA, 2011d). EPA assessed the acute and chronic aggregate exposure levels and corresponding potential risk and concluded that there are no residue chemistry, toxicological, or occupational/residential exposure issues that would preclude the establishment of an unconditional registration or permanent tolerances for isoxaflutole and diketonitrile on soybean and aspirated soybean grain fractions (EPA, 2011e). Establishment of a tolerance for isoxaflutole on soybean concludes that there is a reasonable certainty that no harm to human health will result from aggregate exposure to isoxaflutole or its residues, including all dietary exposures and all other exposures for which there is reliable information (76 FR 235, 2011). When used according with EPA label restrictions, the established tolerances of isoxaflutole on soybean and aspirated soybean grain fractions are unlikely to adversely affect human health. Direct exposure of workers to pesticides is discussed in Subsection 4.5.2 – Worker Safety.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of FG72 Soybean does not impact human health.

4.5.2 Worker Safety

No Action Alternative: Worker Safety

Under the No Action Alternative, FG72 Soybean continues to be regulated by APHIS, and the current availability of GE, non-GE and organic soybeans does not change. Agronomic practices used for soybean production and discussed in Subsection 2.1 and 4.2 – Agricultural Production of Soybean, do not change.

These agricultural practices include the application of agricultural chemicals (pesticides and fertilizers). Growers will experience the continued emergence of glyphosate-resistant weeds, requiring modifications of crop management practices to address these weeds. These changes may include diversifying the MOA of herbicides applied to soybean and making adjustments to crop rotation and tillage practices (Owen et al., 2011a; Norsworthy et al., 2012). Herbicide use may increase to meet the need for additional integrated weed management tactics to mitigate herbicide-resistant weeds in different cropping systems (Owen, 2008; Heap, 2013). Growers choose certain pesticides based on weed, insect and disease pressures, cost of seed and other inputs, technology fees, human safety, potential for crop injury, and ease and flexibility of the production system (Loux et al., 2012).

EPA's WPS (40 CFR Part 170) was published in 1992 to require actions to reduce the risk of pesticide poisonings and injuries among agricultural workers and pesticide handlers. The WPS offers protections to more than two and a half million agricultural workers who work with pesticides at more than 560,000 workplaces on farms, forests, nurseries, and greenhouses. The WPS contains requirements for pesticide safety training, notification of pesticide applications, use of personal protective equipment, restricted entry intervals following pesticide application, decontamination supplies, and emergency medical assistance.

As discussed in Subsection 2.4 – Public Health, pesticide application represents the primary exposure route to pesticides for farm workers. However, common farm practices, training, and specialized equipment can mitigate exposure to pesticides by farm workers. Worker safety is taken into consideration by EPA in the pesticide registration process and reregistration process. Pesticides are regularly reevaluated by EPA for each pesticide to maintain its registered status under FIFRA. As noted in Subsection 2.4.2 – Worker Safety, EPA pesticide labels provide specific management and handling guidelines intended to reduce the risk of harm to agricultural workers.

It is noteworthy to acknowledge that isoxaflutole is already used in American agriculture. Table 5 illustrates the use of many different herbicides on soybean. APHIS assumes that agricultural workers applying isoxaflutole, glyphosate, and other pesticides adhere to pesticide label precautions, restrictions and guidelines.

When use is consistent with the label, pesticides present minimal risk to the worker. No changes to current worker safety are anticipated under the No Action Alternative.

<u>Preferred Alternative: Worker Safety</u>

Under the Preferred Alternative, cultivation practices and corresponding worker exposures to agronomic inputs are unlikely to change, with the possible exception of a change in use of certain herbicides for weed management.

As noted in Subsection 4.2 – Agricultural Production, Bayer demonstrates in its petition that the agronomic inputs required to cultivate FG72 soybean are functionally equivalent to those required for conventional soybean (Bayer, 2011c; USDA-APHIS, 2012d). Accordingly, the health and safety protocols currently employed by farm workers in the cultivation of soybean do not require changes to accommodate the cultivation of FG72 soybean.

The EPA evaluated potential human health effects to pesticide handlers and applicators (EPA, 2011d). As with all pesticides, the EPA considers worker exposure from mixing, loading, application, and entering a previously treated work site (EPA, 2011d). Based on information provided in existing APHIS EAs (USDA-APHIS, 2012b), the potential worker health risks associated with glyphosate use is expected to be similar to the No Action Alternative. The EPA has determined that isoxaflutole had low acute toxicity via the oral, dermal, and inhalation routes, it is neither a dermal irritant, an eye irritant nor a dermal sensitizer (EPA, 2011d). As a result of this human health risk assessment, EPA classified isoxaflutole as "likely to be a human carcinogen" however, the carcinogenic risk is estimated to be below EPA’s established level of concern for life-time cancer risk (EPA, 2011d). The EPA determined that with the use of protective gloves, all mixer, loader, applicator exposures did not present a risk concern (EPA, 2011d). Estimated occupational handler cancer risks are below EPAs target level of concern with the use of gloves as recommended by the label (EPA, 2011d).

APHIS assumes that the application of isoxaflutole to FG72 soybean is conducted consistent with current practices in soybean and other crops. Similar to other herbicides, the EPA label restrictions include standard practices intended to minimize harm to growers and agricultural workers. In the case of isoxaflutole, these measures include requirements that applicators and other handlers must wear long-sleeved shirts and long pants, chemical resistant gloves, shoes and socks, and protective eyewear (Bayer, 2011b). When mixing, loading, or cleaning equipment workers must wear a chemical resistant apron in addition to the other required PPE (Bayer, 2011b). APHIS further assumes that agricultural workers applying isoxaflutole herbicides to FG72 soybean adhere to these label restrictions and guidelines.

Based on these findings, APHIS has determined that approval of a petition for nonregulated status of FG72 soybean will not impact worker safety.

4.6 Animal Feed

No Action Alternative: Animal Feed

The majority of the soybean cultivated in the U.S. is grown for animal feed and is usually fed as soybean meal. Under the No Action Alternative, soybean-based animal feed will still be available from currently cultivated conventional varieties, including GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. This includes herbicide-resistant GE soybean varieties. As discussed in Subsection 4.5 – Human Health, pesticide residue tolerances have been published for glyphosate and isoxaflutole (EPA, 2012c). No change in the availability of these crops as animal feed is expected under the No Action Alternative.

Preferred Alternative: Animal Feed

APHIS' assessment of the potential direct impacts of the consumption of FG72 soybean as animal feed considers the source of the gene and the expressed protein and safety evaluations conducted by Bayer. Indirect impacts consider the potential for exposure to pesticide residues associated, in this case, with the cultivation of an herbicide-resistant crop.

Under FFDCA, it is the responsibility of feed manufacturers to ensure that the products they market are safe and properly labeled. Feed derived from FG72 soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for feed may undergo a voluntary consultation process with the FDA prior to release onto the market. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 5, 2009. . The FDA completed its consultation and as of August 7, 2012 has no further questions (FDA, 2012a).

A determination of nonregulated status of FG72 soybean is unlikely to adversely affect the nutrition of animal feed, and thus, animal health. The two introduced proteins in FG72 soybean, 2mEPSPS and HPPD W336, are unlikely to substantially affect the nutritional quality of soybean meal derived from FG72 soybean. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, demonstrating that it is not likely to have any significant impact on animal health (USDA-APHIS, 1997; CFIA, 1998; FSANZ, 2001; SCF, 2002). Though HPPD W336 has not previously been evaluated in animal feed, there is no reason to suspect it would present a substantial risk to animal health. HPPD proteins are ubiquitous in the environment. Additionally, bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c).

With regard to FG72 soybean itself, compositional analysis revealed no substantial differences between it and conventional soybean in factors important for animal feed, such as proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations (Bayer, 2011c). Consequently, the quality of animal feed derived from FG72 soybean is unlikely to be substantially different than animal feed produced from current soybean varieties.

With regard to indirect exposure to pesticides through animal feed ingestion of treated commodities, the EPA reviews potential consumption and develops a pesticide residue tolerance. As glyphosate and isoxaflutole herbicides are currently used, pesticide tolerance levels have been established for a wide variety of commodities, including soybean (EPA, 2012d). For glyphosate, the tolerance for soybean seed is 20 parts per million (ppm) (EPA, 2012c), while the established tolerance of isoxaflutole is 0.05 ppm (EPA, 2012c).

Based on these findings, approval of a petition for nonregulated status of FG72 soybean is unlikely to impact animal feed.

4.7 Socioeconomic Impacts

4.7.1 Domestic Economic Environment

No Action Alternative: Domestic Economic Enivonrment

In 2012, 77 million acres of soybeans were cultivated in the U.S., yielding 3.0 billion bushels at a value of 43.2 billion U.S. dollars (USDA-NASS, 2013h). The majority of soybeans produced in the U.S. are utilized domestically for animal feed, with less amounts and byproducts used for oil or fresh consumption (GINA, 2011; USDA-ERS, 2012b). Total acreage planted to soybeans in the US is projected to remain at 2012 levels in 2013, then falling slightly to 76 million acres for 2014 through 2021. Average yields are projected to increase from 44.5 bushels per acre in 2013 to 48.1 bushels/acre in 2021 (USDA-OCE, 2012).

Under the No Action Alternative, FG72 soybean and its progeny would remain regulated under 7 CFR part 340. Growers and other parties who are involved in production, handling, processing, or consumption of soybean would not have access to FG72 soybean and its progeny, but would continue to have access to conventional soybean varieties, including GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Domestic growers will continue to utilize conventional soybean varieties based upon availability and market demand.

Contemporary soybean crop management practices include specific measures to protect and preserve varietal identity, as well as a wide range of agronomic inputs. These management practices vary from grower to grower, and are unaffected by the No Action Alternative. Management practice considerations associated with the current cultivation of herbicide resistant soybeans would include adherence to label use restrictions for any herbicides applied to the crop.

Growers adopting GE varieties incur a cost premium to acquire the seed (NRC, 2010a). These technology fees are imposed by the product developer to cover their research and development costs, and GE seeds are traditionally more expensive than conventional seed (NRC, 2010a).

Growers cultivating GE crops all pay such technology fees. The NRC suggests that the benefits associated with the adoption of GE crops, including a reduction in agronomic inputs and increases in yield outweigh the extra costs of the GE seed (NRC, 2010a). All growers adopting GE crops would incur these fees. These costs are unaffected by the No Action Alternative.

The continued emergence of glyphosate-resistant weed biotypes has been identified as an economic concern (NRC, 2010a). Glyphosate-resistant weed biotypes have been demonstrated to reduce the effectiveness and economic benefits of glyphosate-resistant crop systems (Owen et al., 2011a; Weirich et al., 2011). Current research advocates using herbicides presenting multiple MOAs to manage these weeds (see, e.g., (Owen et al., 2011a). Growers would select other herbicides based on the targeted weed and herbicide resistance traits of the targeted weed (Purdue, 2012). Isoxaflutole is one such herbicide offering another MOA to control glyphosate-resistant weeds.

To manage herbicide-resistant weeds, growers have increased herbicide application rates, increased the number of herbicide applications, and have returned to more traditional tillage practices (Sandell et al., 2009; NRC, 2010a). The economic impacts of glyphosate-resistant weeds are a direct result of increased inputs: additional herbicides are required to control the weeds; fuel costs increase as heavy equipment is used more frequently in the field for chemical application; and tillage and labor and management hours increase in association with the application of additional herbicides and machinery use (NRC, 2010a; Weirich et al., 2011). There is an additional cost from the reduction in yield associated with the competition of the crop with the weeds (NRC, 2010a; Weirich et al., 2011).

Under the No Action Alternative, growers will continue to benefit from the adoption and cultivation of GE crops, including the commensurate reduction in costs associated with tillage and pesticide applications (Duke and Powles, 2009). At the same time, those growers managing herbicide-resistant weeds would incur increased costs to employ a wide range of management techniques, including increased pesticide use and increased tillage. These trends are unaffected by the No Action Alternative.

Preferred Alternative: Domestic Economic Environment

The commercialization of FG72 soybean is unlikely to have significant impact on the total acreage planted to soybeans, as larger market forces that influence the price of soybeans are more influential in the planting decisions that growers make. Adopters of FG72 soybean may realize savings in weed management costs through reduced expenditure on herbicides, reduced application costs for growers who reduce the number of trips across the field, and reduced tillage costs. In addition, growers who are experiencing yield losses due to competition from glyphosate resistant weeds may avoid these losses through improved weed control. The short term benefits of the introduction of the technology will be highly dependent on the price of the technology and herbicide to growers, which will also impact the extent of adoption.

Soybean composition greatly affects its viability as a component of animal feed. Soybean meal generally contains 50 percent protein by dry weight and is an important component of soybean production. An additional 19 percent (by weight) of domestically chorused soybeans are used to produce oil (USB, 2011a). The fatty acid content of soybean grain is important for the domestic soybean oil industry, as the soybean oil profile affects melting point, oxidative stability, and chemical functionality, ultimately determining the market value/marketability of the product (APAG, 2011).

A determination of nonregulated status of FG72 soybean is expected to have similar impacts on the domestic economic environment as the No Action Alternative. Paired comparison of FG72 soybean with its nontransgenic, parent variety demonstrated no significant differences in fatty acid or crude protein content (Figure 13). Thus, market sector use of FG72 soybean under the Preferred Alternative is unlikely to be substantially different from market use of Jack, as the primary factors of oil and protein content are not substantially different between the two soybean varieties.

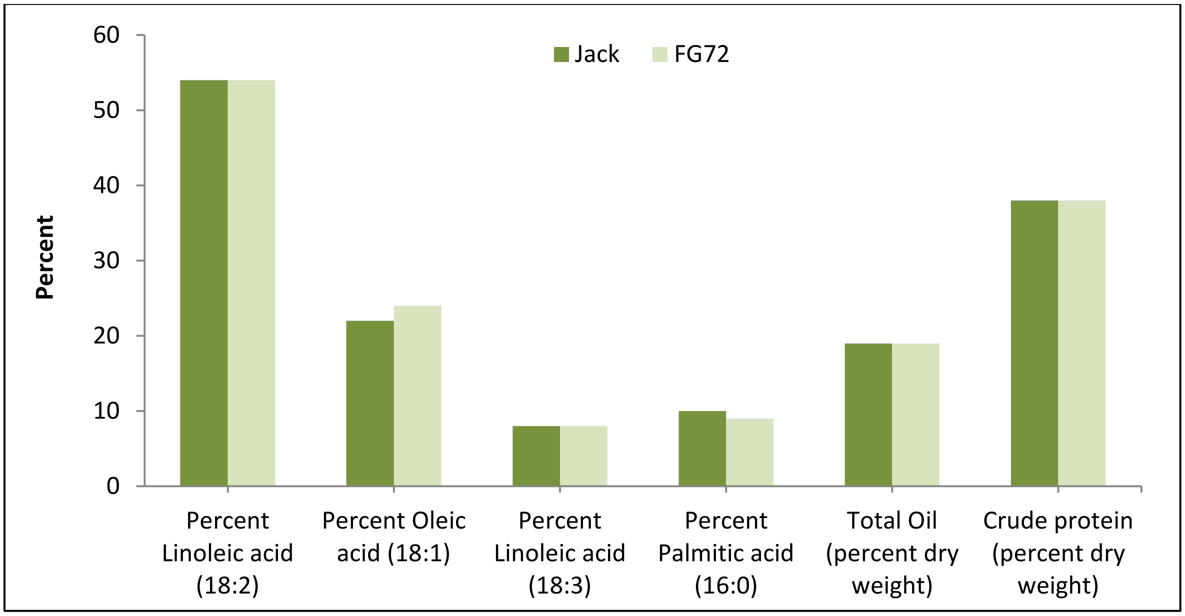


Figure 13. Comparison of typical soybean fatty acids and crude protein between FG72 soybean and Jack. Source: Bayer(Bayer, 2011c)**.**

The long term benefits of FG72 soybean are dependent on the stewardship of the technology by farmers with respect to the implementation of integrated weed management programs that could delay or prevent the further development of herbicide resistant weeds. The benefits of FG72 soybean with respect to controlling glyphosate resistant weeds will depend on the avoidance of the development of isoxaflutole-resistance in the same weed species that are currently resistant to glyphosate, or may become resistant in the future.

Under the Preferred Alternative, trends related to the domestic economic environment are unlikely to be substantially different than what would occur in the No Action Alternative.

4.7.2 Organic Soybean Production

No Action Alternative: Organic Soybean Production

Current availability, market demand, and acreage of organic soybean are anticipated to remain unchanged under the No Action Alternative. Similar to market trends for other U.S. organic products, demand of organic soybean is likely to increase (USDA-ERS, 2007). Despite this increasing demand, however, the share of U.S. organic soybean production remains relatively small and steady. While this flat production of U.S. organic soybean correlates with an increase in GE soybean adoption, there is little or no evidence to suggest a cause-and-effect relationship. An alternative explanation is that U.S. organic soybean acreage remains limited because of unrelated reasons, such as: 1) the three-year period transition period between conventional and organic farming; 2) a lack of contractors for organic agronomic practices, including pest and nutrient management; 3) intensive labor requirements; 4) fear of criticism from neighbors; 5) An absence of government infrastructure and policy support; and 6) unknown risks (Clarkson, 2007; USDA-ERS, 2007).

From 2005 - 2008, total organic soybean acreage ranged between 100,000 and 126,000 acres (USDA-ERS, 2010b). This represented less than 0.2 percent of the total U.S. soybean acreage for this period and is not anticipated to substantially change in spite of rising domestic demand, due in part to increasing competition and imports from international organic soybean producers (USDA-ERS, 2007). Therefore, domestic demand for organic soybean and organic soybean products appear to be sustained by increasing imports from international organic soybean producers (The Organic & Non-GMO Report, 2007; USDA-ERS, 2007).

Preferred Alternative: Organic Soybean Production

It is not likely that organic farmers will be substantially affected by a determination of nonregulated status of FG72 soybean. Soybean is primarily a self-pollinated plant (OECD, 2010), and there is no reason to suspect that the biology of FG72 soybean will increase its potential to outcross with soybean varieties utilized in organic soybean production (USDA-APHIS, 2012d). Field studies of FG72 soybean reproductive biology revealed no substantial differences in factors influencing reproductive potential, including pollen viability, date of emergence, date of 50 percent flowering, and date of maturity (Bayer, 2011c).

It is important to note that the current NOP regulations do not specify an acceptable threshold level for the adventitious presence of GE materials in a product labeled organic (USDA-ERS, 2010b). The unintentional presence of the products of excluded methods will not affect the status of an organic product or operation when the operation has not used excluded methods and has taken reasonable steps to avoid contact with the products of excluded methods (Ronald and Fouche, 2006; USDA-AMS, 2010). However, certain markets or contracts may have defined thresholds (Non-GMO-Project, 2010).

A determination of nonregulated status of FG72 soybean is unlikely to substantially affect U.S. organic soybean market conditions. In contrast to other U.S. organic crops, U.S. organic soybean production has not kept pace with demand (USDA-ERS, 2010b). Domestic production of organic soybean has not kept pace with demand due to the reasons outlined in the previous No Action Alternative section. The increased demand for organic soybean in the U.S. has generally been met by increasing imports from international organic soybean producers (The Organic & Non-GMO Report, 2007; USDA-ERS, 2007).

4.7.3 Trade Economic Environment

<u>No Action Alternative: Trade Economic Environment</u>

The U.S. produces approximately 33 percent of the global soybean supply (Soy Stats, 2012b). In 2011, the U.S. exported 1.3 billion bushels of soybean, which accounted for 37 percent of the world's soybean exports (USDA-FAS, 2013). The global demand for soybeans is expected to increase by a full third over 2011 consumption in the next ten years. China is expected to account for 93 percent of the increased demand (Hartnell, 2010; FAPRI, 2012). China is predicted to import 69 percent of the total soybean market by 2021/2022 (FAPRI, 2012). The USDA has predicted that U.S. exports will remain flat during much of this period, as a result of increase in domestic consumption and competition from South America (FAPRI, 2012; USDA-ERS, 2013d).

Under the No Action Alternative, there is unlikely to be any change to the current soybean market. Most (93 percent) of the soybean varieties currently cultivated in the U.S. are GE varieties and it is predicted that this will not change substantially (USDA-ERS, 2012a). U.S. soybeans will continue to play a role in global soybean production, and the U.S. will continue to be a supplier in the international market.

<u>Preferred Alternative: Trade Economic Environment</u>

A determination of nonregulated status of FG72 soybean is not expected to adversely impact international soybean markets. To the extent that adoption of FG72 soybean allows growers to reduce weed control costs, its introduction may enhance US competitiveness in global markets. To support commercial introduction of FG72 soybean in the U.S., Bayer intends to submit dossiers to request import approval of FG72 soybean to the proper regulatory authorities of several countries that already have regulatory processes for GE soybean in place. These include, but are not limited to: Canada, Mexico, Japan, the EU, South Korea, and China (Bayer, 2011c; Coates, 2012). In general, a global launch (i.e., commercialization) may not be undertaken until the proper regulatory approvals have been obtained (Coates, 2012). Approval in these export countries is intended to mitigate global sensitivities to GE productions and work in accordance with international regulations. The trade economic impacts associated with a determination of nonregulated status of FG72 soybean are anticipated to be very similar to the No Action Alternative.

5 CUMULATIVE IMPACTS

A cumulative impact may be an effect on the environment which results from the incremental impact of the proposed action when added to other past, present, and reasonably foreseeable future actions. For example, this may include the potential effects associated with a determination of nonregulated status for a GE crop in combination with the future production of crop seeds with multiple deregulated traits (i.e., "stacked" traits), including drought tolerance, herbicide resistance, and pest resistance, would be considered a cumulative impact. A cumulative impact may also include the use of a pesticide with a similar mode of action to that of the intended pesticide described in the petition for nonregulated status.

5.1 Assumptions Used for Cumulative Impacts Analysis

Potential environment effects regarding specific issues associated with approval of a petition for nonregulated status for FG72 soybean have been analyzed and addressed in Section 4. In this EA, the cumulative effects analysis is focused on the incremental impacts of the Preferred Alternative taken in consideration with related activities, including past, present, and reasonably foreseeable future actions. Certain aspects of this product and its cultivation would be no different between the alternatives; those instances are described below. In this analysis, if there are no direct or indirect impacts identified for a resource area, then APHIS assumes there can be no cumulative impacts. Where it is not possible to quantify impacts, APHIS provides a qualitative assessment of potential cumulative impacts.

Stacked soybean varieties may contain more than one GE trait as the result of crossing two GE soybean plants. Under the Preferred Alternative, FG72 soybean may be crossed with non-GE or GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (USDA-APHIS, 2012c). APHIS regulations at 7 CFR Part 340 do not provide for Agency oversight of GE soybean varieties no longer subject to the requirement of Part 340 and the plant pest provisions of the Plant Protection Act, or over stacked varieties combining these GE varieties, unless it can be positively shown that such stacked varieties were to pose a likely plant pest risk. With regard to FG72 soybean, there is no indication in the Bayer FG72 soybean petition or international import approval application packages that FG72 soybean will be stacked with any specific GE or non-GE soybean trait (Bayer, 2011c; EFSA, 2011b; FSANZ, 2011a). Even with regard to possible stacking with Bayer's glufosinate-resistant soybean (98-238-01p and 96-068-01p), there exists uncertainty in the development of that particular product, as glufosinate is described as a potential herbicide to control volunteer FG72 soybean in the Bayer petition (Bayer, 2011c). There is no assurance that FG72 soybean will be stacked with any particular GE or non-GE soybean trait, as company plans and market demands play a major role in those business decisions. Therefore, predicting all potential combinations of stacked varieties from current GE and non-GE soybean varieties is hypothetical and speculative.

Nonregulated GE glyphosate- resistant (e.g., Roundup Ready®) crop varieties have been in the market since 1996, when glyphosate- resistant soybean became commercially available. The potential effects from the cultivation of glyphosate- resistant crops, with a corresponding analysis of the implications of the use of glyphosate, have been thoroughly evaluated in other APHIS EAs since the 1993 introduction of the first glyphosate- resistant crop product (see http://www.aphis.usda.gov/biotechnology/not_reg.html). Several of these evaluations included crops expressing resistance to multiple herbicides. Specific crop examples include:

- Sugar Beet, 2011. Monsanto and KWS SAAT AG Glyphosate- resistant Sugar Beet (Petition No. 03-023-01p).
- Soybean, 2011. Monsanto Improved Fatty Acid Profile Soybean (which includes glyphosate resistance) (Petition No. 09-201-01p).
- Alfalfa, 2011. Monsanto Glyphosate- resistant Alfalfa (Petition 04-110-01p).
- Corn, 2009. Pioneer Glyphosate and Imadazolinone- resistant Corn (Petition 07-152-01p).
- Cotton, 2009. Bayer Crop Science Glyphosate- resistant Cotton (Petition 06-332-01p).
- Soybean, 2008. Pioneer Glyphosate and Acetolactate Synthase- resistant Soybean (Petition No. 06-271-01p).
- Soybean, 2007. Monsanto Glyphosate- resistant Soybean (Petition 06-178-01p).
- Cotton, 2005. Monsanto Glyphosate- resistant Cotton (Petition 04-086-01p).
- Rapeseed 2001. Monsanto Glyphosate- resistant Rapeseed (Petition 01-324-01p).
- Corn, 2000. Monsanto Glyphosate- resistant Corn (Petitions No. 97-099-01p and 00-011-01p).
- Rapeseed 1998. Monsanto Glyphosate- resistant Rapeseed (Petition 98-216-01p).
- Sugar Beet, 1998. Novartis Seeds and Monsanto Glyphosate- resistant Sugar Beet (Petition No. 98-173-01p).
- Corn, 1997. Monsanto Glyphosate- resistant Corn (Petition No. 97-099-01p).
- Corn, 1996. Monsanto Glyphosate- resistant and European Corn Borer-resistant Corn (Petition No. 96-317-01p).
- Cotton, 1995. Monsanto Glyphosate- resistant Cotton (Petition 95-045-01p).
- Soybean, 1993. Monsanto Glyphosate- resistant Soybean (Petition 93-258-01p).

The first glyphosate- resistant soybean became commercially available to growers in 1996 after Monsanto's Roundup Ready® Soybean (GTS 40-3-2) was determined to be no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act (see APHIS Petition File 93-258-01p at http://www.aphis.usda.gov/biotechnology/not_reg.html).

5.2 Cumulative Impacts: Range and Acreage of Soybean Production

Cumulative effects resulting from a determination of nonregulated status of FG72 soybean on acreage and range of soybean production are unlikely. The Preferred Alternative is not expected to directly cause a change in agricultural acreage devoted to conventional or GE soybean cultivation in the U.S. and there are no anticipated changes to the availability of GE and non-GE soybean varieties on the market. GE soybean varieties already constitute a large proportion of U.S. soybean production (93 percent) (USDA-ERS, 2012a); cultivation of FG72 soybean with current GE soybean varieties is unlikely to substantially change this pattern of adoption, as it represents a replacement and not supplemental soybean variety for U.S. soybean growers.

Acreage of soybean production is primarily dependent on market demand; cultivation and associated production practices of FG72 soybean are unlikely to disrupt this causal relationship, as U.S. soybean production is strongly affected by market demand, not by any one soybean variety (USDA-ERS, 2012b; USDA-ERS, 2013d). Furthermore, the range of soybean cultivation is unlikely to be impacted by a determination of nonregulated status of FG72 soybean. FG72 soybean generally does not present an absolute yield gain under standard management conditions and does not display a phenotype that would be indicative of an improved capacity to grow outside an agricultural environment (USDA-APHIS, 2012d). Similar to currently-available soybean varieties, FG72 soybean is likely to require cultivation on high quality arable land to be profitable. Consequently, FG72 soybean is unlikely to encourage cultivation on marginal land, thus maintaining currently-observed farm-level land-use decisions to shift agricultural land away from other crops, such as cotton or hay, toward soybean production to satisfy market demand (USDA-ERS, 2011c; USDA-ERS, 2013d).

For these reasons, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to impact soybean acreage and areas of production.

5.3 Cumulative Impacts: Agronomic Practices

Agronomic practices related to soybean production are often dependent on the particular soybean variety cultivated. FG72 soybean possesses similar agronomic requirements and pest sensitivities as conventional soybean, and thus, is not anticipated to have any cumulative effect on current and general soybean agronomic practices, such as fertilization, rotational, and pesticide application practices (USDA-APHIS, 2012d).

Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage (USDA-NASS, 2007a; NRC, 2010a). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on agronomic practices are likely. A determination of nonregulated status of FG72 soybean would permit the use of isoxaflutole in addition to glyphosate. Application of isoxaflutole over FG72 soybean is unlikely to result in any cumulative effect on current conservation tillage practices because isoxaflutole provides control over a range of weed species including many glyphosate resistant weeds (Bayer, 2011b; Syngenta, 2011). Furthermore, application of isoxaflutole, does not result in common corn rotational restrictions (Bayer, 2011b; Syngenta, 2011).

Taken in total, application of isoxaflutole in FG72 soybean is unlikely to result in a cumulative effect on herbicide use, as restrictions on use, reduced application rate, and residual control post application of isoxaflutole may limit use of this herbicide relative to glyphosate in soybean production systems.

Based on the above information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to affect changes in tillage, crop rotation, or agronomic inputs.

5.4 Cumulative Impacts: Soil Quality

A determination of nonregulated status of FG72 soybean is unlikely to result in a cumulative impact on soil quality. Comprehensive phenotypic, agronomic, and ecological assessments conducted by the petitioner for FG72 soybean did not find substantial differences between FG72 soybean and control soybeans for these characteristics (Bayer, 2011c). The few differences that were identified were typically small, site specific, and unlikely to be biologically meaningful. Event FG72 soybean required similar agronomic practices as non-GE soybean (Bayer, 2011c). Consequently, the phenotypic, agronomic, and ecological data presented in the Bayer petition support the conclusion by APHIS that FG72 soybean will not substantially modify soil characteristics associated with typical soybean production practices. In particular, FG72 soybean will permit the continued use of conservation tillage, an agricultural practice with strong direct and positive effects on soil quality (Holland, 2004; NRC, 2010a).

The cultivation of a stacked variety resistant to herbicides with multiple modes of action may benefit soil quality. This benefit derives from growers' ability to manage hard to control weeds using the herbicides with multiple modes of action rather than revert to conventional tillage (Steckel and Montgomery, 2008; Price et al., 2011). Avoiding conventional tillage, and the continuation and expansion of conservation tillage, can result in continued improvements to soil quality. Such an approach is consistent with the management strategies currently advocated in the industry (Duke and Powles, 2009; Norsworthy et al., 2012; Vencill et al., 2012).

Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010a). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on soil quality are likely. Isoxaflutole may be applied to FG72 soybean production fields. Isoxaflutole is a 4-HPPD inhibitor. Isoxaflutole does not persist in soil, as indicated by photolysis, aerobic and anaerobic soil metabolism, and field dissipation studies(EPA, 1998). Any impact directly from soil quality as a result of isoxaflutole application is most likely to affect rotational crops that may be planted sometime after isoxaflutole application. For this purpose, rotational restrictions are described on the EPA use label, indicating which crops are safe to plant (See Sppendix A). The presence of these rotational restrictions is not inherently any different than rotational restrictions with currently used soybean herbicides.

Based on the above information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on soil resources.

5.5 Cumulative Impacts: Water Resources

A determination of nonregulated status is unlikely to result in a cumulative impact on water resources related to soybean production. This conclusion is based on the fact that cultivation of FG72 soybean is likely to permit the continued use of conservation tillage, and thus, maintain its indirect and positive effects on water quality and runoff. The agronomic performance of FG72 soybean is similar to conventional soybean, suggesting that FG72 soybean does not require more irrigation than currently-available soybean varieties (Bayer, 2011c; USDA-APHIS, 2012d).

Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage. Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on water quality are likely. Isoxaflutole is not anticipated to result in any cumulative effect on water quality, because it does not persist in soil or aqueous environments (EPA, 2008; EPA, 2011h). Furthermore, while isoxaflutole may be mobile in water, the leaching potential of this compound is not substantially greater than current herbicides commonly utilized in soybean production, suggesting that it poses no greater leaching risk to water resources (NY State IPM Program, 2012). EPA label use restrictions on isoxaflutole use mitigate groundwater and surface water quality risks by restricting use of isoxaflutole to areas where groundwater and surface water contamination are unlikely. To the extent that different herbicides with multiple modes of action are applied to FG72 soybean varieties, APHIS assumes that growers apply the herbicides based on EPA's label requirements, including adherence to label requirements to protect water resources. EPA's FIFRA registration process ensures that each registered pesticide continues to meet the highest standards of safety to protect human health and the environment.

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on water resources.

5.6 Cumulative Impacts: Air Quality

APHIS has not identified any cumulative effects for this issue resulting from a determination of nonregulated status of FG72 soybean. APHIS does not anticipate any substantial changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of FG72 soybean. Agricultural practices will continue to have the potential to cause negative impacts to air quality. Agricultural emission sources will continue to include smoke from agricultural burning, tillage, traffic and harvest emissions, and nitrous oxide emissions from the use of nitrogen fertilizer. These agricultural emissions sources are anticipated to be similar between conventional soybean varieties and cultivation of FG72 soybean.

As discussed in Subsection 4.3.3 – Air Quality, to the extent that growers adopt FG72 soybean, and by so doing, avoid conventional tillage by adopting a management strategy using herbicides with multiple modes of action, the cultivation of FG72 soybean could result in air quality benefits. These same benefits can accrue from the cultivation of stacked varieties resistant to multiple herbicides. These benefits would arise from a reduction or avoidance of entrainment of soils in the atmosphere associated with tillage, and a corresponding reduction or elimination of emissions from farm equipment used to conduct this tillage. There is also a corresponding benefit associated with the sequestration of carbon and nitrogen in the soils as vegetative matter in the soil is allowed to decompose in the subsoil environment.

APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on air quality.

5.7 Cumulative Impacts: Climate Change

APHIS has not identified any cumulative effects on climate change following a determination of nonregulated status of FG72 soybean. APHIS does not anticipate any substantial changes in soybean production practices or an expansion of soybean acreage as a result of a determination of nonregulated status of FG72 soybean. The consequences of the Preferred Action Alternative on commercial soybean production and acreage are the same as for the No Action Alternative.

FG72 soybean would enable growers to use a combination of herbicides with different modes of action on soybean, an approach proposed to mitigate the future development of herbicide-resistant weeds (Duke and Powles, 2009). Based on individual grower needs, this approach may reduce the need to use more aggressive tillage to control glyphosate-resistant weeds (Owen, 2011), which could potentially impact conservation tillage. The continued use of conservation tillage associated with GE crops may reduce GHG emissions as a result of increased carbon sequestration in soils, decreased fuel consumption, and the reduction of nitrogen soil amendments (Towery and Werblow, 2010).

It is possible that climate change may affect soybean cultivation areas in the U.S. For example, as projected by the U.S. Global Change Research Program (CCSP, 2009), the northern regions of the Great Plains may become wetter while the southern regions may become drier. However, these shifts are unlikely to uniquely affect FG72 soybean, as there is no reasonable expectation that this soybean variety would require less moisture or possess a cultivation range that is different than conventional soybean.

APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an impact on climate change.

5.8 Cumulative Impacts: Animal Communities

Under field conditions, soybean or soybean grain may be used by mammals, birds, or arthropods. Bayer data demonstrates that the composition of FG72 soybean does not substantially differ from conventional soybean varieties (USDA-APHIS, 2012d). The FDA has completed its consultation on the safety of FG72 soybean as animal feed (FDA, 2012a). Both APHIS and Food Standards Australia New Zealand (FSANZ) have concluded that FG72 soybean is compositionally similar to conventional soybean (FSANZ, 2011a; USDA-APHIS, 2012d). This indicates that FG72 soybean is unlikely to result in a cumulative effect on animal communities through consumption.

Pesticides are applied on a majority of U.S. soybean acres, with herbicides representing the majority of pesticide applications (USDA-NASS, 2007a; NRC, 2010a). Nontarget insects are unlikely to be substantially affected by insecticide application practices in FG72 soybean compared to conventional soybean, as insecticide application patterns are similar between FG72 and conventional soybean (USDA-APHIS, 2012d).

Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage (USDA-NASS, 2007a; NRC, 2010a). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on animals are likely. The potential application of isoxaflutole poses little risk to birds, mammals, fish, and the honey bee (EPA, 2011b; EPA, 2011h).

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on animal communities.

5.9 Cumulative Impacts: Plant Communities

The focus of the analysis of potential cumulative impacts to plant communities is on the management of herbicide-resistant weeds and whether the cultivation of FG72 soybean might result in an incremental increase in the probability of multiple MOA resistant weeds. Before discussing this issue, it is prudent to briefly note other potential areas of impact.

A determination of nonregulated status of FG72 soybean is unlikely to have any cumulative effect on plant communities beyond what is already occurring in soybean production. The introduced proteins in FG72 soybean, 2mEPSPS and HPPD W336, are derived from organisms that are non-pathogenic and/or non-toxic to plants; these proteins are effectively benign in the environment (Bayer, 2011c). There are no wild relatives of soybean in the U.S. This eliminates any gene transfer between FG72 and non-domesticated plants (OECD, 2010). Furthermore, FG72 soybean does not display weedy characteristics and is not expected to be a weed (USDA-APHIS, 2012d).

As discussed in Subsections 4.3.3 – Air Quality, and 4.4.2 – Plant Communities, plant communities associated with the cultivation of GE herbicide-resistant crops might be potentially indirectly impacted by the growers' use of herbicides as a function of drift and volatilization. As noted in Subsection 1.1 – Coordinated Framework Review and Regulatory Review, APHIS has no jurisdiction over risks resulting from the use of herbicides or other pesticides. The EPA has the responsibility pursuant to FIFRA to determine the potential off-target impacts of herbicide use on plants when it conducts the ecological risk analysis during the label registration process. These labels provide specific use restrictions and application guidelines to minimize off-target impacts, including restrictions on specific directions and restrictions for nozzle height, spray pressure and wind speed. APHIS expects that growers and pesticide applicators continue to adhere to these label use guidelines and restrictions.

Cultivation of FG72 soybean will permit the use of glyphosate and isoxaflutole to control weed populations. Glyphosate is already widely applied in U.S. soybean production fields (USDA-NASS, 2007a; NRC, 2010a; Bonny, 2011). Since FG72 soybean is resistant to glyphosate, it is unlikely to disrupt current glyphosate use patterns and its effect on plant communities.

Isoxaflutole is a broad-spectrum herbicides that has not previously been utilized in soybean production. Isoxaflutole represents another herbicide in a growing diversity of herbicides utilized in soybean production and is not likely to result in a cumulative impact on weed species relative to other herbicides currently utilized in U.S. soybean production.

FG72 soybean can only be adopted in those states where isoxaflutole is registered for use (Figure 7). Within those states there are specific label instructions for applying isoxaflutole that would further restrict its use on soybeans (see Appendix A). Because of the restricted availability for isoxaflutole use, FG72 soybean production is expected to be limited and not likely to result in a cumulative impact to plant communities relative to other herbicides currently used in soybean production.

Herbicide resistance in weeds has become one of the most pressing issues facing contemporary agriculture (WSSA, 2012). Herbicide-resistant weeds predate the introduction of glyphosate-resistant crops. As glyphosate-resistant crops were introduced as a solution to weeds resistant to other herbicides, the wide-spread emergence of glyphosate-resistance in weeds has provoked an extensive dialog in the agricultural community on how to best implement weed management practices that both provide for efficient weed control and avoid selection of herbicide-resistant weeds (Norsworthy et al., 2012; WSSA, 2012). As noted above, the focus of this subsection is on the question of whether the cultivation of FG72 soybean might result in an incremental increase in the probability of multiple MOA resistant weeds.

Herbicide-resistant weeds are problematic in many states. As noted in Subsection 2.3.2 – Plant Communities, in the United States, 76 weed species have developed resistance to at least 17 herbicide MOAs (Heap, 2013). Currently, fourteen glyphosate-resistant weeds have been identified in the United States, of which ten glyphosate-resistant weeds have been identified in U.S. soybean fields (Figure 4) (Heap, 2013).

Weed populations can change in response to farm-level agronomic practices, including weed management decisions. Cultivation of FG72 soybean may provide some utility in the control of glyphosate-resistant weeds because isoxaflutole represents a broad-spectrum herbicide with an alternative MOA to glyphosate. With respect to glyphosate-resistant weeds that may be found in U.S. soybean fields, isoxaflutole can be expected to control horseweed, kochia, Palmer amaranth, spiny amaranth, common and giant ragweed, goosegrass, Italian ryegrass and johnsongrass(Table 28) (Bayer, 2011a).

Table 27. Glyphosate-resistant weed (in soybean fields) control profiles for isoxaflutole.

Broadleaf Weeds*	**Isoxaflutole control/suppression**
Horseweed (Marestail) (*Conyza candensis*)	Yes
Kochia (*Kochia scoparia*)	Yes
Palmer Amaranth (*Amaranthus palmeri*)	Yes
Spiny amaranth (*Amaranthus spinosus*)	Yes
Common ragweed (*Ambrosia artemisiifolia*)	Yes
Giant ragweed (*Ambrosia trifida*)	Yes
Common waterhemp (*Amaranthus tuberculatus*)	No**
Goosegrass (*Eleusine indica*)	Yes
Italian ryegrass (*Lolium spp. multiflorum*)	Yes
Johnsongrass (*Sorghum halepense*)	Yes

*Only certain weed populations demonstrate glyphosate resistance.
** Resistant biotypes found in Iowa.
Sources: (Bayer, 2011b) and (Heap, 2013).

Weed biotypes resistant to multiple MOAs have been reported in many locales. Since 2009, four populations of common waterhemp in Illinois, Iowa, and Nebraska were reported to be resistant to 4-HPPD inhibitors (Heap, 2011). Despite the four reported cases, only one waterhemp population (McLean County, IL) was studied in detail (Syngenta, 2010; Hausman et al., 2011). In the McLean County population (which also possessed non-target site atrazine resistance), development of 4-HPPD resistance was generally linked to seed corn production and its respective management strategies that precluded the application of pre-emergent and broad-spectrum herbicides. As a result, 4-HPPD inhibitors were used without MOA rotation over the course of seven growing seasons (2003 – 2009) (Hausman et al., 2011). Further examination of this waterhemp population revealed that control could be achieved through several common agricultural strategies, including the pre-emergent application of 4-HPPD inhibitors and post-emergent foliar application of broad-spectrum herbicides, such as glyphosate and glufosinate (Syngenta, 2010).

While the McLean County population of waterhemp demonstrated that the development of resistance to 4-HPPD inhibitors is possible, it also underscored the value of herbicide chemistry rotation (alternative MOA) across growing seasons and the utility of pre-emergent herbicide application in weed control. Effective management, however, does not ensure that herbicide use is intrinsically sustainable. Herbicide use (and indirectly, the use of herbicide- resistant crops) is sustainable only as a component of a broader integrated weed management system (Mortensen et al., 2012) and that the preemptive incorporation of integrated weed management measures may prevent or mitigate the development of a resistant weed population (Bayer, 2011c). Agricultural weed development is not necessarily limited to herbicide use, but may also develop in response to cultural methods not reliant on herbicide use (Vaughan et al., 2008).

To reduce or mitigate against the selective pressures associated with the use of a single weed management practice, agronomists have recommended that growers adopt a diverse weed management strategy (Norsworthy et al., 2012; HRAC, 2013). Thus, integrated weed management does not exclude any one management technique. It incorporates a number of practices, including the use of cover and rotational crops, tillage, and herbicide applications to reduce selection pressure and weed populations in an agroenvironment (Mortensen et al., 2012). Integrated weed management programs that use herbicides from different groups, vary cropping systems, rotate crops, and use mechanical as well as chemical weed control methods will prevent the selection of herbicide-resistant weed populations (Powles, 2008; Green and Owen, 2011; Sellers et al., 2011; Gunsolus, 2012). It is only through the development and implementation of an integrated weed management program utilizing as wide a variety of weed control practices as are economically feasible that the problem can be effectively managed or prevented (HRAC, 2013). As part of its integrated weed management plan for FG72 soybean, Bayer has proposed the following in its stewardship of FG72 soybean (Bayer, 2011c):

- Correctly identify weeds and look for trouble areas within field to identify resistance indicators;
- Rotate crops;
- Start the growing season with clean fields;
- Rotate herbicide MOA by using multiple MOAs during the growing season and apply no more than two applications of a single herbicide MOA to the same field in a two-year period. One method to accomplish this is to rotate herbicide- resistant trait systems;

- Apply recommended rates of herbicides to actively growing weeds at the correct time with the right application techniques;
- Control any weeds that may have escaped the herbicide application; and
- Thoroughly clean field equipment between fields.

Where diversity in weed management systems is maintained, weed control by herbicides can be sustainable (Powles and Yu, 2010). Weed management practices will vary by crop and by region, ecosystem, economics and many other factors; diversity will involve herbicide rotations/sequences, mixtures of robust rates of herbicides with different MOAs, and the use of non-herbicide weed controls (Powles and Yu, 2010). The application of herbicides with alternative MOAs can reduce selection pressure when the herbicides provide redundant control of weeds (HRAC, 2013). When selecting an appropriate herbicide rotation, the grower must be cognizant of the biology of the weeds present as weed species each have a unique range of response to herbicides (Norsworthy et al., 2012).

The simplicity and flexibility of the glyphosate-resistant crop/glyphosate combination to control virtually all weed species eliminated the need for agronomic consultants to provide prescription herbicide combination solutions dependent upon crop type, herbicide selectivity, and weed spectrum (Duke and Powles, 2009).

The cumulative impact of the introduction of FG72 soybean will ultimately depend on the adoption by farmers of diverse weed management practices. The implementation by growers of strategies to reduce or delay the onset of herbicide-resistant weeds is highly variable (Vencill et al., 2012). The costs associated with weed prevention and management and the grower's immediate needs, including economic constraints and crop rotations, are important considerations in the decision of whether and when to implement herbicide-resistance mitigation strategies (Vencill et al., 2012). Survey data suggest that growers have already adopted many of the recommended herbicide-resistance management practices to delay the selection of herbicide-resistant weeds. For example, grower survey data for Indiana corn and soybean growers in 2003 and 2004 reported that more than 80% of the growers had already adopted, or were willing to adopt, herbicide-resistance management practices by scouting for weeds, using soil-applied herbicides, using 2,4-D or dicamba with glyphosate for a pre-plant burndown, and using POST tank mixtures (Givens et al., 2009; Vencill et al., 2012). In a 2007 survey of cotton, corn, and soybean growers across the United States, 70% of cotton growers reported practicing seven or more resistance-management practices, compared with 58% of corn producers and 55% of soybean producers (Frisvold et al., 2009).

Cultivation of FG72 soybean may potentially allow a more comprehensive approach to weed management. Crop and herbicide rotation are two factors that may mitigate the development of herbicide resistance in weeds. As stated previously in this EA, there is reason to believe that FG72 soybean would benefit from crop rotation (similar to commercial soybean varieties), and that FG72 soybean would permit the use of two herbicides with different MOAs, followed by use of an alternative MOA in the next growing season (e.g., glufosinate). Utilized within an integrated weed management system and within the context of best management practices, a determination of nonregulated status of FG72 soybean may positively contribute to the control of glyphosate-resistant weed populations while also reducing the development of other herbicide resistance.

The cumulative impact of the introduction of FG72 soybean will ultimately depend on the adoption by farmers of diverse weed management practices. Diverse weed management practices are recommended to minimize selective pressure for herbicide-resistant weeds. Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on plant communities.

5.10 Cumulative Impacts: Gene Flow and Weediness

As described in the APHIS PPRA for FG72 soybean, no substantial differences are observed in pollen viability, pollen morphology, or seed dormancy (Bayer, 2011c; USDA-APHIS, 2012d). Given the reproductive characteristics of soybean, the probability for cross-pollination is low (Caviness, 1966; Ray et al., 2003). While cross-pollination can occur between adjacent plants and adjacent rows, it is unlikely that FG72 soybean would be grown in the same fields as other soybean varieties. Consequently, the barriers that exist between different soybean varieties and sexually-compatible soybean varieties would likely continue to act as limitations on gene flow without any cumulative effect on gene flow. The soybean industry has identity protection (IP) measures in place to restrict pollen movement and gene flow between soybean fields through the use of isolation distances, border and barrier rows, the staggering of planting dates and various seed handling, transportation, and cleaning procedures (Sundstrom et al., 2002; NCAT, 2003; Bradford, 2006). Furthermore, FG72 soybean represents a domesticated soybean variety that would not be anticipated to survive outside the agricultural environment, indicating that cultivation of FG72 soybean may not result in a cumulative effect on plant weediness.

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on gene movement and weediness.

5.11 Cumulative Impacts: Microorganisms

Cultivation of FG72 soybean is unlikely to have a cumulative effect on soil microorganisms relative to the cultivation of conventional soybean varieties, including GE soybean varieties that are no longer subject to the regulatory requirements of 7 CFR part 340 or the plant pest provisions of the Plant Protection Act. Microbial activity in agricultural soil is often strongly dependent on cultivation conditions, with the primary effectors representing crop type, seasonality, prevalent soil properties, and tillage strategy (Holland, 2004; Hart et al., 2009). When generally compared to existing soybean production practices, cultivation of FG72 will utilize similar management conditions, such as the continuation of conservation tillage, seasonal rotation of soybean with additional crops, and broad use of herbicides. In particular, the majority of U.S. soybean acres are sprayed with glyphosate and other herbicides. FG72 soybean will permit the continuation of this existing trend, as it will permit the application of glyphosate and isoxaflutole. Because any microorganism is already extensively exposed to herbicides in current U.S. soybean production fields, it is unlikely that any new microorganism would be affected through production practices associated with FG72 soybean or its progeny.

Based on the above information, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have a negative impact on microorganisms.

5.12 Cumulative Impacts: Biodiversity

Cultivation of FG72 soybean is unlikely to have toxic effects on non-target animals and microorganisms. Additionally, cultivation of FG72 soybean is likely to be neutral with regard to biodiversity compared with typical GE and non-GE soybean production systems, due to similar management conditions for both production systems. As discussed in Subsection 4.4.5 – Biodiversity, Bayer has presented results of field and laboratory studies indicating that FG72 soybean is substantially equivalent to conventional soybean varieties in terms of required agronomic inputs, phenotypic and morphological characteristics, and composition (Bayer, 2011c). Application of herbicides in U.S. soybean production will continue to be dictated by both individual farm need and EPA label use restrictions. As a consequence of its herbicide registration program, EPA has effectively determined that there is no unreasonable environmental risk if the end user adheres to the directions and restrictions on the EPA registration label when applying herbicide formulations. When required, application by a certified applicator further minimizes effects on biodiversity. Since violators of requirements are liable and can be held legally accountable for all negative consequences of their actions, this responsibility serves as an additional safeguard against any adverse cumulative effects on non-target organisms and biodiversity from the use of EPA restricted use pesticides.

As discussed in Subsections 2.3.5 and 4.4.5 – Biodiversity, as growers continue to apply herbicides with multiple MOA, herbicide-resistant weeds are expected to decline (Norsworthy et al., 2012). The use of GE soybean varieties containing herbicide- resistant traits may improve biological diversity by providing growers the opportunity to use conservation tillage practices (NRC, 2010a; Bonny, 2011). Incorporation of herbicide resistance in the crop facilitates the grower adoption of conservation and no-till strategies, improved soil porosity, enhancing soil fauna and flora (CTIC, 2010), increasing the flexibility of crop rotation, and facilitating strip cropping (Fernandez-Cornejo et al., 2002). Any such avoidance or minimization of conventional tillage through the use of herbicides benefits biodiversity through decreased soil erosion, improved water quality, retention of vegetative over and crop residues providing a food source, and increased populations of invertebrates providing food sources to other organisms (Landis et al., 2005; Sharpe, 2010). Each of these contributes to the health of the faunal and floral communities in and around soybean fields thereby promoting biodiversity (Palmer et al., 2010).

APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on biodiversity.

5.13 Cumulative Impacts: Public Health

A determination of nonregulated status of FG72 soybean is not anticipated to result in any cumulative effect on human health. As discussed in Subsection 4.5, Bayer has presented data comparing the phenotypic, morphological and compositional characteristics of FG72 soybean with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Bayer, 2011c). No biologically meaningful differences were identified between FG72 soybean and other varieties. FG72 soybean is compositionally equivalent to conventional soybean (USDA-APHIS, 2012d). Therefore, consumption of FG72 soybean is expected to be as safe as consumption of conventional soybean. FSANZ has already determined that FG72 soybean is as whole and nutritious as conventional soybean (FSANZ, 2011a; FSANZ, 2011b). Food derived from GE soybean must be in compliance with all applicable legal and regulatory requirements. GE organisms for food may undergo a voluntary consultation process with the FDA prior to release onto the market. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 5, 2009. The FDA completed its consultation and as of August 7, 2012 has no further questions (FDA, 2012a).

With regard to herbicide exposure, growers already utilize a wide range of herbicides and tank mixes of herbicides to control weeds in soybean (Loux et al., 2012; Zollinger, 2013). EPA considers the human health effects of exposure to herbicides when conducting pesticide registration reviews and determining label application rates and use restrictions. Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010a). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on human health are likely. Human exposure to isoxaflutole, either indirectly through residue on soybean grain or directly through soybean production in the field, is not expected to result in a cumulative impact on human health. Pesticide tolerances have been established for isoxaflutole on soybean, so no unnecessary risk to human health from residues resulting from application at approved labeled use rates are anticipated (74 FR 67119, 2009; 76 FR 235, 2011). Human health risk assessments for isoxaflutole have generally indicated that the herbicide poses no unnecessary risk to human health (EPA, 2009b; EPA, 2011d). Additionally, registration and application of these pesticides will also continue to be regulated by EPA, ensuring that there is no unnecessary risk for both the general public and agricultural workers.

The total amount of the mix of herbicides that may be applied to FG72 soybean would be used in accordance with per application and per year rates approved by EPA. When used consistently with the EPA label, pesticides present minimal risk to human health and worker safety. APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on human health.

5.14 Cumulative Impacts: Animal Feed

FG72 soybean is not anticipated to result in any cumulative effect on animal feed. Bayer has presented compositional data comparing the phenotypic and morphological characteristics of FG72 soybean with other varieties, including bioinformatics analysis of allergenicity, toxicity, nutrients and anti-nutrients, and amino acid homology, among others (Bayer, 2011c; USDA-APHIS, 2012d). No biologically meaningful differences were identified between FG72 soybean and other varieties. The introduced proteins in FG72 soybean are not toxic or allergic. Since the composition of FG72 is similar to conventional soybean varieties, this also serves as a good indicator that negative effects on feed quality containing FG72 soybean grain are unlikely

(Bayer, 2011c). FSANZ has already determined that FG72 soybean is as whole and nutritious as conventional soybean (FSANZ, 2011a; FSANZ, 2011b). Additionally, Bayer presented the results of a feeding study involving an acute toxicity study where mice were fed FG72 2mEPSPS and HPPD W336 proteins (Bayer, 2011c). There were no adverse effects noted in the highest dose level tested (Bayer, 2011c). As noted in Subsection 4.6 – Animal Feed, Bayer has completed a voluntary biotechnology consultation with the FDA for FG72 soybean. As part of this evaluation, the FDA considers the product identity, function, characterization of the genes, expression of the genes and resulting proteins, and safety of the protein and product. The FDA has concluded that FG72 soybean is not materially different in any respect relevant to feed safety compared to soybean varieties already on the market (FDA, 2012a).

As discussed in Subsection 1.3 – Coordinated Framework Review and Regulatory Review, the EPA considers pesticide residues on crop commodities as part of its pesticide registration process, and establishes residue tolerance limits pursuant to its authority under the FFDCA (EPA, 2012d). Farmers that grow FG72 soybean may apply glyphosate and isoxaflutole. Glyphosate is already applied on the majority of U.S. soybean acreage (NRC, 2010a). Therefore, cultivation of FG72 soybean is unlikely to change current glyphosate use patterns, so no cumulative effects on animal feeds are likely. Animals may be exposed to isoxaflutole through residue on soybean grain that is added to animal feed. This exposure route is not expected to result in a cumulative impact on animal health. Pesticide tolerances have been established for isoxaflutole on soybean, so residues resulting from application at recommended rates are not anticipated to pose any unnecessary risks (74 FR 67119, 2009; 76 FR 235, 2011).

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on animal feed.

5.15 Cumulative Impacts: Domestic Economic Environment

It is unlikely that the commercial cultivation of FG72 soybean would result in cumulative socioeconomic impacts to domestic economics at either the farm or the market level.

Domestically-produced soybean and soybean products are produced for a number of markets. Market use of soybean is often dependent on the soybean variety, and thus composition, produced. There are compositional differences among some soybean varieties grown for animal feed and those for human consumption. FG72 soybean is compositionally similar to its non-GE comparator, Jack (Bayer, 2011c). Thus, market use of FG72 soybean should be similar to that of Jack. With regard to ensuring the quality of soybean animal feed, because of the general absence of plant reproductive attributes that could affect gene flow, it is unlikely that FG72 soybean would present any additional issue beyond those already discussed for conventional soybean varieties.

As discussed in Subsection 4.7.1 –Domestic Economic Environment, adopters of FG72 soybean may realize savings in weed management costs through reduced expenditure on herbicides as certain herbicides are eliminated by the introduction of more effective weed control strategies, lowered application costs for growers who eliminate one or more equipment trips across the field, and decreased tillage costs as tillage is replaced with herbicide applications. In addition, growers who are experiencing yield losses due to competition from glyphosate resistant weeds may avoid these losses through improved weed control. Cultivation of soybean varieties resistant to herbicides with multiple modes of action can allow growers to take full advantage of current recommendations for best management strategies to reduce the risks of herbicide-resistant weeds (Norsworthy et al., 2012). The short term benefits of the introduction of the technology will be highly dependent on the price of the technology and herbicide to growers, which will also impact the extent of adoption.

In the long term, the cumulative socioeconomic impacts of FG72 soybean will depend on stewardship of the technology by farmers with respect to the implementation of integrated weed management programs that could delay or prevent the further development of herbicide resistant weeds. To the extent that FG72 soybean is one of several GE herbicide-resistant technologies that growers will have to choose from, with corresponding herbicides from different herbicide groups, selection pressure for the development of herbicide resistant weeds may be reduced.

With respect to the potential for increased market concentration in the soybean seed market, the availability of several GE herbicide-resistant soybean technologies may have the effect of increasing competition compared to a situation where fewer technologies are available. The extent to which the introduction of new GE herbicide-resistant soybean technologies have any impact on soybean seed market concentration will likely be related to farmers' perceptions of the benefits of the technologies and resulting adoption rates.

APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action that would have an adverse impact on the domestic economic environment.

5.16 Cumulative Impacts: Trade Economic Environment

It is unlikely that the commercial cultivation of FG72 soybean results in cumulative socioeconomic impacts to the trade economic environment. Although the primary U.S. soybean export destinations do not present major barriers to trade in GE products, Bayer would need to obtain FG72 soybean approval in destination countries before commercialization in the U.S. to avoid adversely affecting current trade flows. Requests for approvals have been submitted to several markets, including, but is not limited to, Canada, Mexico, Japan, the EU, South Korea, and China. Bayer has previously stated its intention to seek approval for FG72 soybean in primary U.S. export destinations with functioning regulatory systems before commercialization in the U.S. (Coates, 2012). Thus, a cumulative effect on the trade economic environment is not anticipated following a determination of nonregulated status of FG72 soybean, because it is unlikely to be commercialized until it is approved for export to major U.S. soybean importing countries.

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that would aggregate with effects of the proposed action to have an impact on the trade economic environment.

5.17 Cumulative Impacts: Organic and Specialty Soybean Production and Marketing

As discussed in Subsection 4.7.2 – Organic Soybean Production, coexistence strategies are currently implemented to protect and preserve soybean varietal integrity in the marketplace; moreover, these strategies are not required to change to accommodate the cultivation of FG72 soybean. Other GE soybean varieties with similar agronomic characteristics would likewise not require any changes by organic and specialty soybean growers.

The availability of FG72 soybean and other new GE soybean varieties adds GE soybean varieties to the conventional soybean market. As discussed in Subsection 4.7.2 – Organic Soybean Production, the recent organic soybean production trends suggest that the addition of GE varieties to the market is not related to the ability of organic production systems to maintain their market share.

Approval of a petition for nonregulated status for FG72 soybean, a variety providing resistance to different herbicides with multiple modes of action, adds another GE variety to the existing soybean market. This process is not expected to change the market demands for GE soybean or soybean produced using specialty systems.

The practices of farmers of organic and other specialty soybeans to manage coexistence and maintain variety identity does not change under the Preferred Alternative. Consumer behavior and choice is unaffected under the Preferred Alternative.

Based on these findings, APHIS has determined that there are no past, present, or reasonably foreseeable actions that aggregate with effects of the proposed action to have an impact on the socioeconomics of organic and specialty production and marketing.

6 THREATENED AND ENDANGERED SPECIES

The Endangered Species Act (ESA) of 1973, as amended, is one of the most far-reaching wildlife conservation laws ever enacted by any nation. Congress, on behalf of the American people, passed the ESA to prevent extinctions facing many species of fish, wildlife and plants. The purpose of the ESA is to conserve endangered and threatened species and the ecosystems on which they depend as key components of America's heritage. To implement the ESA, the U.S. Fish & Wildlife Service (USFWS) works in cooperation with the National Marine Fisheries Service (NMFS), other Federal, State, and local agencies, Tribes, non-governmental organizations, and private citizens. Before a plant or animal species can receive the protection provided by the ESA, it must first be added to the Federal list of threatened and endangered wildlife and plants.

A species is added to the list when it is determined by the USFWS/NMFS to be endangered or threatened because of any of the following factors:

- The present or threatened destruction, modification, or curtailment of its habitat or range;
- Overutilization for commercial, recreational, scientific, or educational purposes;
- Disease or predation;
- The inadequacy of existing regulatory mechanisms; and
- The natural or manmade factors affecting its survival.

Once an animal or plant is added to the list, in accordance with the ESA, protective measures apply to the species and its habitat. These measures include protection from adverse effects of Federal activities.

Section 7 (a)(2) of the ESA requires that Federal agencies, in consultation with USFWS and/or the NMFS, ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. It is the responsibility of the Federal agency taking the action to assess the effects of their action and to consult with the USFWS and NMFS if it is determined that the action "may affect" listed species or critical habitat. This process is used by APHIS to assist the program in fulfilling their obligations and responsibilities under Section 7 of the ESA for biotechnology regulatory actions.

As part the environmental review process, APHIS thoroughly reviews GE product information and data to inform the ESA effects analysis and, if necessary, the biological assessment. For each transgene(s)/transgenic plant the following information, data, and questions are considered by APHIS:

- A review of the biology, taxonomy, and weediness potential of the crop plant and its sexually compatible relatives;

- Characterization of each transgene with respect to its structure and function and the nature of the organism from which it was obtained;

- A determination of where the new transgene and its products (if any) are produced in the plant and their quantity;

- A review of the agronomic performance of the plant including disease and pest susceptibilities, weediness potential, and agronomic and environmental impact;

- Determination of the concentrations of known plant toxicants (if any are known in the plant); and

- Analysis to determine if the transgenic plant is sexually compatible with any threatened or endangered plant species (TES) or a host of any TES.

In following this review process, APHIS, as described below, has evaluated the potential effects that a determination of nonregulated status of FG72 soybean may have, if any, on Federally-listed TES and species proposed for listing, as well as designated critical habitat and habitat proposed for designation. Based upon the scope of the EA and production areas identified in the Affected Environment section of the EA, APHIS obtained and reviewed the USFWS list of TES species (listed and proposed) for each state where soybean is commercially produced from the USFWS Environmental Conservation Online System(USFWS, 2013). Prior to this review, APHIS considered the potential for FG72 soybean to extend the range of soybean production and also the potential to extend agricultural production into new natural areas. Bayer's studies demonstrate that agronomic characteristics and cultivation practices required for FG72 soybean are essentially indistinguishable from practices used to grow other soybean varieties, including other herbicide-resistant varieties (Bayer, 2011c; USDA-APHIS, 2012d). Although FG72 soybean may be expected to replace other varieties of soybean currently cultivated, APHIS does not expect the cultivation of FG72 soybean to result in new soybean acres to be planted in areas that are not already devoted soybean production. Accordingly, the issues discussed herein focus on the potential environmental consequences of the determination of nonregulated status of FG72 soybean on TES species in the areas where soybean are currently grown.

APHIS focused its TES review on the implications of exposure to the 2mEPSPS and HPPD W336 proteins in FG72 soybean, the interaction between TES and FG72 soybean, including the potential for sexual compatibility and the ability to serve as a host for a TES; and potential impacts of the use of glyphosate and isoxaflutole herbicides to non-target organisms and the natural environment.

6.1 Potential Effects of FG72 Soybean on TES

<u>Threatened and Endangered Plant Species</u>

The agronomic data provided by Bayer were used in the APHIS analysis of the weediness potential for FG72 soybean and further evaluated for the potential to impact TES. Agronomic studies conducted by Bayer tested the hypothesis that the weediness potential of FG72 soybean is unchanged with respect to conventional soybean (Bayer, 2011c; USDA-APHIS, 2012d). No differences were detected between FG72 soybean and conventional soybean in growth, reproduction, or interactions with pests and diseases, other than the intended effect of herbicide resistance (USDA-APHIS, 2012d). Potential of soybean weediness is low, due to domestication syndrome traits that generally lower overall fitness outside an agricultural environment (Stewart et al., 2003). Mature soybean seeds have no innate dormancy, are sensitive to cold, and are not expected to survive in freezing winter conditions (Raper and Kramer, 1987). Soybeans have been cultivated around the globe without any report that it is a serious weed or that it forms persistent feral populations (USDA-APHIS, 2012d). Soybean cannot survive in the majority of the country without human intervention, and it is easily controlled if volunteers appear in subsequent crops. APHIS has concluded the determination of nonregulated status of FG72 soybean does not present a plant pest risk, does not present a risk of weediness, and does not present an increased risk of gene flow when compared to other currently cultivated soybean varieties. Based on the agronomic field data and literature survey on soybean weediness potential, FG72 soybean is unlikely to affect TES as a troublesome or invasive weed (USDA-APHIS, 2012d).

APHIS evaluated the potential of FG72 soybean to cross with a listed species. As discussed above and in the analysis of Gene Movement and Weediness, APHIS has determined that there is no risk to unrelated plant species from the cultivation of FG72 soybean. Soybean is highly self-pollinating and can only cross with other members of *Glycine* subgenus *Soja*. Wild soybean species are endemic in China, Korea, Japan, Taiwan and the former USSR; in the U.S. there are no *Glycine* species found outside of cultivation and the potential for outcrossing is minimal (OECD, 2010). After reviewing the list of threatened and endangered plant species in the U.S. states where soybean is grown, APHIS determined that FG72 soybean would not be sexually compatible with any listed threatened or endangered plant species proposed for listing, as none of these listed plants are in the same genus nor are known to cross pollinate with species of the genus *Glycine*.

Based on the agronomic field data, literature survey on soybean weediness potential, and that there are no TES sexually compatible with soybean, APHIS has concluded that FG72 soybean will have no effect on threatened or endangered plant species.

Threatened and Endangered Animal Species

Threatened and endangered animal species that may be exposed to the gene products in FG72 soybean would be those TES that inhabit soybean fields and feed on FG72 soybean. To identify potential effects on threatened and endangered animal species, APHIS evaluated the risks to threatened and endangered animals from consuming FG72 soybean. Soybean commonly is used as a feed for many livestock. Additionally, wildlife may use soybean fields as a food source, consuming the plant, grain, or insects that live on the plants. However, TES generally are found outside of agricultural fields. Few if any TES are likely to use soybean fields because they do not provide suitable habitat. Only whooping crane (*Grus americana*), sandhill crane (*Grus canadensis pulla*), piping plover (*Charadrius melodus*), and interior least tern (*Sterna antillarum*) (USFWS, 2011a). These bird species may visit soybean fields during migratory periods, but would not be present during normal farming operations (Krapu et al., 2004; USFWS, 2011a). In a study of soybean consumption by wildlife in Nebraska, results indicated that soybeans do not provide the high energy food source needed by cranes and waterfowl (Krapu et al., 2004). The Delmarva fox squirrel (*Sciurus niger cinereus*), which inhabits mature forests of mixed hardwoods and pines, may be found adjacent to agricultural areas of the Delmarva Peninsula (USFWS, 2011b). This species feeds primarily on acorns, nuts, and pine seeds and is not likely to utilize soybeans to any extent. The Louisiana black bear (*Ursus americanus luteolus*), occurring in Louisiana, Mississippi, and Texas (Johnsen et al., 2005), may occasionally forage on soybean; however, other crops such as corn, sugarcane, and winter wheat are preferred by this species (MSU Extension Service, Undated).

FG72 soybean is genetically engineered to show 2mEPSPS and HPPD W336 protein accumulation, and thus, herbicide resistance to glyphosate and isoxaflutole. 2mEPSPS has been previously analyzed and approved by several international regulatory agencies, thus demonstrating that it is not likely to have any significant impact on animal health (USDA-APHIS, 1997; CFIA, 1998; FSANZ, 2001; SCF, 2002). The food and feed safety of 2mEPSPS has been assessed in these products and shown to present no food or feed safety risk. Though HPPD W336 has not previously been evaluated, there is no reason to suspect it would present a risk to non-target organisms. HPPD proteins are ubiquitous in the environment and are not novel. Bioinformatic analysis of HPPD W336 showed no significant lengthwise alignment with known toxins or allergens (Bayer, 2011c).

FG72 soybean is within the scope of the FDA policy statement concerning regulation of products derived from new plant varieties, including those produced through genetic engineering. Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 5, 2009. FDA completed evaluating the submission, and as of August 7, 2012, has no further questions concerning food and feed derived from FG72 soybean (FDA, 2012a).

Bayer CropScience has presented data on the food and feed safety of FG72 soybean, evaluating the agronomic and morphological characteristics of FG72 soybean, including compositional and nutritional characteristics, safety evaluations, and toxicity tests, as compared to a conventional soybean variety (Bayer, 2011c). Compositional elements, including proximate and fiber components, amino acid and fatty acid content, and antinutrients and isoflavone concentrations, revealed no substantial differences between FG72 soybean and conventional soybean varieties (Bayer, 2011c). As discussed in Section 4.4 and 4.6, the data collected indicate there is no difference in the composition and nutritional quality of FG72 soybean compared with conventional soybean varieties, apart from the presence of the 2mEPSPS and HPPD W336 proteins. Food Standards Australia New Zealand (FSANZ) also determined that FG72 soybean are compositionally similar to conventional soybean, thus suggesting that FG72 soybean is unlikely to result in an effect on threatened and endangered animal species (FSANZ, 2011a; FSANZ, 2011b). The results presented by Bayer show that the incorporation of the *2mepsps* and *hppd w336* genes and the accompanying activity of the 2mEPSPS and HPPD W336 proteins in FG72 soybean does not result in any biologically-meaningful differences between FG72 soybean and non-GE hybrids.

Because there is no toxicity or allergenicity potential with FG72 soybean, there would be no direct or indirect toxicity or allergenicity impacts on wildlife species that feed on soybean or the associated biological food chain of organisms. Therefore, based on these analyses, APHIS concludes that consumption of FG72 soybean plant parts (seeds, leaves, stems, pollen, or roots) would have no effect on any listed threatened or endangered animal species or animal species proposed for listing.

After reviewing the possible effects of allowing the environmental release of FG72 soybean, APHIS has not identified any stressor that could affect the reproduction, numbers, or distribution of a listed TES or species proposed for listing. APHIS also considered the potential effect of a determination of nonregulated status of FG72 soybean on designated critical habitat or habitat proposed for designation, and could identify no differences from effects that would occur from the production of other soybean varieties. Soybean is not considered a particularly competitive plant species and has been selected for domestication and cultivation under conditions not normally found in natural settings (OECD, 2001; OECD, 2010). Soybean is not sexually compatible with, nor serves as a host species for, any listed species or species proposed for listing. Consumption of FG72 soybean by any listed species or species proposed for listing will not result in a toxic or allergic reaction. Based on these factors, APHIS has concluded that a determination of nonregulated status of FG72 soybean, and the corresponding environmental release of this soybean variety will have no effect on listed species or species proposed for listing, and would not affect designated habitat or habitat proposed for designation. Because of this no effect determination, consultation under Section 7(a)(2) of the Act or the concurrences of the USFWS or NMFS are not required.

6.2 Potential Effects of the use of Glyphosate and Isoxaflutole

APHIS met with USFWS officials on June 15, 2011, to discuss whether APHIS has any obligations under the ESA regarding analyzing the impacts of herbicide use associated with all GE crops on TES. As a result of these joint discussions, USFWS and APHIS have agreed that it is not necessary for APHIS to perform an ESA effects analysis on herbicide use associated with GE crops currently planted because EPA has both regulatory authority over the labeling of pesticides and the necessary technical expertise to assess pesticide effects on the environment under FIFRA. APHIS has no statutory authority to authorize or regulate the use of glyphosate and isoxaflutole, or any other herbicide, by soybean growers. Under APHIS' current Part 340 regulations, APHIS only has the authority to regulate FG72 soybean or any GE organism as long as APHIS believes it may pose a plant pest risk. For GE organisms, APHIS has no regulatory jurisdiction over any other risks associated with GE organisms including risks resulting from the use of herbicides or other pesticides on those organisms. Nevertheless, APHIS is aware that there may be potential environmental impacts resulting from the use of glyphosate and isoxaflutole on FG72 soybean, including potential impacts on TES and critical habitat, based on assessments performed by the EPA and as available in the peer reviewed scientific literature. APHIS is providing the available information of potential environmental impacts resulting from glyphosate and isoxaflutole use on FG72 soybean below.

<u>Endangered Species Protection Program</u>

In 1988, Congress enacted Public Law 100-478 (October 7, 1988) to in part address the relationship between ESA and EPA's pesticide labeling program (Section 1010), which required EPA to conduct a study, and report to Congress, on ways to implement EPA's endangered species pesticide labeling program in a manner that both complies with ESA and allows people to continue production of agricultural food and fiber. This law provided a clear sense that Congress wanted EPA to fulfill its obligation to conserve listed species, while at the same time consider the needs of agriculture and other pesticide users (211 FR 66392, 2005).

In 1988, EPA established the Endangered Species Protection Program (ESPP) to meet its obligations under the ESA. EPA's ESPP site[31] describes the EPA assessment process for endangered species. Some of the elements of that process, as reported on the website, are summarized below. The goal of EPA's ESPP is to carry out its FIFRA responsibilities in compliance with the ESA, without placing unnecessary burden on agriculture and other pesticide users consistent with Congress' intent.

EPA is responsible for reviewing pesticide information and data to determine whether a pesticide product may be registered for a particular use, including those uses associated with the approval of biotechnology products. As part of that determination, the Agency assesses whether listed endangered or threatened species or their designated critical habitat may be affected by use of the pesticide product. All pesticide products that EPA determines "may affect" a listed species or its designated critical habitat may be subject to the ESPP. If limitations on pesticide use are necessary to protect listed species in areas where a pesticide may be used, the information is related through Endangered Species Protection Bulletins. Bulletins identify the species of concern and the pesticide active ingredient that may affect the listed species. They also provide a description of the measures necessary to protect the species and contain a county-level map showing the geographic area(s) associated with the protection measures, depending on the susceptibility of the species. Bulletins are enforceable as part of the product label (EPA, 2011a).

<u>EPA TES Evaluation Process</u>

EPA evaluates listed species and their critical habitat concerns within the context of pesticide registration and registration review so that when a decision is made, it fully addresses issues relative to listed species protection. If a risk assessment determines that use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, EPA may either change the terms of the pesticide registration or establish geographically specific pesticide use limitations (EPA, 2011a). The use of any pesticide in a manner that may kill or otherwise harm an endangered species or adversely modify their habitat is a violation of federal law. Pesticides must be used in accordance with the restrictions specified on their product labels.

EPA's review of the pesticide and its registration decision is independent of APHIS' review and regulatory decisions under 7 CFR 340. EPA does not require data or analyses conducted by APHIS to complete its reviews. EPA evaluates extensive toxicity, ecological effects data, and environmental fate, transport and behavior data, most of which is required under FIFRA data requirements, to assess and determine how a pesticide will move through and break down in the environment. Risks to various taxa, e.g., birds, fish, invertebrates, plants and mammals are routinely assessed and used in EPA's determinations of whether a pesticide may be licensed for use in the U.S.

EPA's core pesticide risk assessment and regulatory processes ensure that protections are in place for all populations of non-target species, not just threatened and endangered species. EPA has developed a comprehensive risk assessment process modeled after, and consistent with, EPA's numerous guidelines for environmental assessments (EPA, 2004). The result of an

[31] http://www.epa.gov/espp/

assessment, which may go through several refinements, is to determine whether the potential effects of a pesticide's registration to a listed species will result in either a "no effect" or "may affect" determination. EPA consults on determinations that "may affect" a listed species or adversely modify its critical habitat (EPA, 2012e). As a result of either an assessment or consultation, EPA may require changes to the use conditions specified on the label of the product. When such changes are necessary only in specific geographic areas rather than nationwide to ensure protection of the listed species, EPA implements these changes through geographically-specific Endangered Species Protection Bulletins, otherwise, these changes are applied to the label for all uses of the pesticide.

Ecological Risks of Glyphosate and Isoxaflutole

Glyphosate and isoxaflutole are registered by the EPA for use in a variety of crops, including soybean (EPA, 2009e; EPA, 2011b). Pursuant to FIFRA Section 3(g), EPA is currently conducting registration reviews for both glyphosate and isoxaflutole to ensure continuing fulfillment of FIFRA registration standards. EPA implements its reregistration eligibility decisions via product reregistration by confirming that required risk reduction measures are reflected on pesticide product labels. The EPA registration reviews for glyphosate and isoxaflutole are scheduled to be completed in 2014 and 2017, respectively (EPA, 2009e; EPA, 2011b).

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide that is widely used to control weeds in agricultural and non-agricultural sites, including forestry, greenhouse, and residential land. Glyphosate was first registered in 1974, and is currently registered for a variety of aquatic and terrestrial uses on fruits, vegetables, and field crops (EPA, 2009a). The effects for glyphosate are summarized in the RED fact sheet and the preliminary problem formulation for the herbicide (EPA, 1993; EPA, 2009e).

Isoxaflutole was conditionally registered on September 15, 1998. The conditional registration was extended on April 11, 2002 and unconditionally registered on October 8, 2004 (Montague, 2012). Isoxaflutole is currently registered as a Restricted Use Pesticide due to non-target phytotoxicity concerns. In contrast to General Use Pesticides, isoxaflutole must be applied by or under the supervision of a certified applicator. At present, EPA is conducting a registration review for isoxaflutole (EPA, 2010e). The results of multiple ecological and human-health risk assessments may be found in Appendix A. In summary, risk to aquatic plants, birds, mammals, invertebrates, and fish were below the EPA level of concern (LOC). Additionally, the EPA human-health risk assessment determined that there is no unreasonable dietary risk surrounding isoxaflutole residues at its established tolerances (EPA, 2011b).

7 CONSIDERATION OF EXECUTIVE ORDERS, STANDARDS, AND TREATIES RELATING TO ENVIRONMENTAL IMPACTS

7.1 Executive Orders with Domestic Implications

The following executive orders require consideration of the potential impacts of the Federal action to various segments of the population.

- ***Executive Order (EO) 12898 (US-NARA, 2010), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,"*** requires Federal agencies to conduct their programs, policies, and activities that substantially affect human health or the environment in a manner so as not to exclude persons and populations from participation in or benefiting from such programs. It also enforces existing statutes to prevent minority and low-income communities from being subjected to disproportionately high and adverse human health or environmental effects.

- ***EO 13045, "Protection of Children from Environmental Health Risks and Safety Risks,"*** acknowledges that children may suffer disproportionately from environmental health and safety risks because of their developmental stage, greater metabolic activity levels, and behavior patterns, as compared to adults. The EO (to the extent permitted by law and consistent with the agency's mission) requires each Federal agency to identify, assess, and address environmental health risks and safety risks that may disproportionately affect children.

The No Action and Preferred Alternatives were analyzed with respect to EO 12898 and EO 13045. Neither alternative is expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

Available mammalian toxicity data associated with the 2mEPSPS and HPPD W336 proteins establish the safety of FG72 soybean and its products to humans, including minorities, low-income populations, and children who might be exposed to them through agricultural production and/or processing. No additional safety precautions would need to be taken.

Based on the information submitted by the applicant and reviewed by APHIS, FG72 soybean is agronomically, phenotypically, and biochemically comparable to conventional soybean except for the introduced 2mEPSPS and HPPD W336 proteins. The information provided in the Bayer petition indicates that the two proteins, 2mEPSPS and HPPD W336, expressed in FG72 soybean are not expected to be allergenic, toxic, or pathogenic in mammals (Rouquié et al., 2010; Bayer, 2011c). Bayer initiated the consultation process with FDA for the commercial distribution of FG72 soybean and submitted a safety and nutritional assessment of food and feed derived from FG72 soybean to the FDA on December 5, 2009. FDA completed its evaluation with no further questions on August 7, 2012.

Human toxicity has also been evaluated by the EPA in its development of pesticide labels for both herbicides (62 FR 17723, 1997); (76 FR 235, 2011). Pesticide labels include use precautions and restrictions intended to protect workers and their families from exposures. It is reasonable to assume that growers will adhere to these EPA herbicide use precautions and restrictions. As discussed in Subsection 4.5, Human Health, the potential use of glyphosate and isoxaflutole on FG72 soybean at the proposed application rates would be no more than rates currently approved by the EPA and should not have adverse impacts to human health when used in accordance with label instructions. It is expected that EPA would monitor the use of FG72 soybean to determine impacts on agricultural practices, such as chemical use, as they have done previously for herbicide-resistant products.

Based on these factors, a determination of nonregulated status of FG72 soybean is not expected to have a disproportionate adverse effect on minorities, low-income populations, or children.

The following executive order addresses Federal responsibilities regarding the introduction and effects of invasive species:

> ***EO 1311 (US-NARA, 2010), "Invasive Species,"*** states that Federal agencies take action to prevent the introduction of invasive species, to provide for their control, and to minimize the economic, ecological, and human health impacts that invasive species cause.

Soybean is not listed in the U.S. as a noxious weed species by the Federal government (ASA, 2011), nor is it listed as an invasive species by major invasive plant data bases. Cultivated soybean seed does not usually exhibit dormancy and requires specific environmental conditions to grow as a volunteer the following year (OECD, 2010). Any volunteers that may become established do not compete well with the planted crop and are easily managed using standard weed control practices. Soybean does not possess characteristics such as the tolerance for a variety of habitat conditions, rapid growth and reproduction, aggressive competition for resources, and the lack of natural enemies or pests (USDA-APHIS, 2012d) that would make it a successful invasive plant. Non-engineered soybeans, as well as other herbicide-resistant soybean varieties, are widely grown in the U.S. Based on historical experience with these varieties and the data submitted by the applicant and reviewed by APHIS, FG72 soybean plants are sufficiently similar in fitness characteristics to other soybean varieties currently grown and are not expected to become weedy or invasive.

The following executive order requires the protection of migratory bird populations:

> ***EO 13186 (US-NARA, 2010), "Responsibilities of Federal Agencies to Protect Migratory Birds,"*** states that federal agencies taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations are directed to develop and implement, within two years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service that shall promote the conservation of migratory bird populations.

Migratory birds may be found in soybean fields. While soybean does not meet the nutritional requirements for many migratory birds (Krapu et al., 2004), they may forage for insects and weed seeds found in and adjacent to soybean fields. As discussed in Sections 4.4.1 and 4.6, data submitted by the applicant has shown no difference in compositional and nutritional quality of FG72 soybean compared with other conventional soybean varieties, apart from the presence of the 2mEPSPS and HPPD W336 proteins. FG72 soybean is not expected to be allergenic, toxic, or pathogenic in mammals. Both 2mEPSPS and HPPD proteins have a history of safe consumption in the context of other food and feeds (Bayer, 2011c). Based on APHIS' assessment of FG72 soybean, it is unlikely that a determination of nonregulated status of FG72 soybean would have a negative effect on migratory bird populations.

The environmental effects associated with isoxaflutole have been analyzed by the EPA (EPA, 2011b; EPA, 2011h). Testing indicates that ecological toxicity of isoxaflutole does not exceed the agency's acute or chronic level of concern. Glyphosate is considered no more than slightly nontoxic to birds (EPA, 1993). Based on these factors, it is unlikely that the determination of nonregulated status of FG72 soybean would have a negative effect on migratory bird populations.

7.2 International Implications

EO 12114 (US-NARA, 2010), "Environmental Effects Abroad of Major Federal Actions" requires federal officials to take into consideration any potential environmental effects outside the U.S., its territories, and possessions that result from actions being taken.

APHIS has given this EO careful consideration and does not expect a significant environmental impact outside the U.S. in the event of a determination of nonregulated status of FG72 soybean. All existing national and international regulatory authorities and phytosanitary regimes that currently apply to introductions of new soybean cultivars internationally apply equally to those covered by an APHIS determination of nonregulated status under 7 CFR part 340.

Any international trade of FG72 soybean subsequent to a determination of nonregulated status of the product would be fully subject to national phytosanitary requirements and be in accordance with phytosanitary standards developed under the International Plant Protection Convention (IPPC, 2010). The purpose of the IPPC "is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control" (IPPC, 2010). The protection it affords extends to natural flora and plant products and includes both direct and indirect damage by pests, including weeds.

The IPPC establishes a standard for the reciprocal acceptance of phytosanitary certification among the nations that have signed or acceded to the Convention (172 countries as of March 2010). In April 2004, a standard for PRA of living modified organisms (LMOs) was adopted at a meeting of the governing body of the IPPC as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11, Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk and that a determination needs to be made early in the PRA for importation as to whether the LMO poses a potential pest risk resulting from the genetic modification. APHIS pest risk assessment procedures for genetically engineered organisms are consistent with the guidance developed under the IPPC. In addition, issues that may relate to commercialization and transboundary movement of particular agricultural commodities produced through biotechnology are being addressed in other international forums and through national regulations.

The *Cartagena Protocol on Biosafety* is a treaty under the United Nations Convention on Biological Diversity (CBD) that established a framework for the safe transboundary movement, with respect to the environment and biodiversity, of LMOs, which include those modified through biotechnology. The Protocol came into force on September 11, 2003, and 160 countries are Parties to it as of December 2010 (CBD, 2010). Although the U.S. is not a party to the CBD, and thus not a party to the Cartagena Protocol on Biosafety, U.S. exporters will still need to comply with those regulations that importing countries which are Parties to the Protocol have promulgated to comply with their obligations. The first intentional transboundary movement of LMOs intended for environmental release (field trials or commercial planting) will require consent from the importing country under an advanced informed agreement (AIA) provision, which includes a requirement for a risk assessment consistent with Annex III of the Protocol and the required documentation.

LMOs imported for food, feed, or processing (FFP) are exempt from the AIA procedure, and are covered under Article 11 and Annex II of the Protocol. Under Article 11, Parties must post decisions to the Biosafety Clearinghouse database on domestic use of LMOs for FFP that may be subject to transboundary movement. To facilitate compliance with obligations to this protocol, the U.S. Government has developed a website that provides the status of all regulatory reviews completed for different uses of bioengineered products (NBII, 2010). These data will be available to the Biosafety Clearinghouse.

APHIS continues to work toward harmonization of biosafety and biotechnology consensus documents, guidelines, and regulations, including within the North American Plant Protection Organization (NAPPO), which includes Mexico, Canada, and the U.S., and within the Organization for Economic Cooperation and Development (OECD). NAPPO has completed three modules of the Regional Standards for Phytosanitary Measures (RSPM) No. 14, *Importation and Release into the Environment of Transgenic Plants in NAPPO Member Countries (NAPPO, 2009).*

APHIS also participates in the *North American Biotechnology Initiative (NABI)*, a forum for information exchange and cooperation on agricultural biotechnology issues for the U.S., Mexico, and Canada. In addition, bilateral discussions on biotechnology regulatory issues are held regularly with other countries including Argentina, Brazil, Japan, China, and Korea.

7.3 Compliance with Clean Water Act and Clean Air Act

This EA evaluated the potential changes in soybean production associated with a determination of nonregulated status of FG72 soybean (Section 4.2) and determined that the cultivation of FG72 soybean would not lead to the increased production or acreage of soybean in U.S. agriculture. The herbicide resistance conferred by the genetic modification to FG72 soybean would not result in any changes in water usage for cultivation. As discussed in Section 4.3.2 and 4.3.3, there are no expected negative impacts to water resources or air quality from potential use of glyphosate or isoxaflutole associated with FG72 soybean production. Based on these analyses, APHIS concludes that a determination of nonregulated status of FG72 soybean would comply with the CWA and the CAA.

7.4 Impacts on Unique Characteristics of Geographic Areas

A determination of nonregulated status of FG72 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farmlands, wetlands, wild and scenic areas, or ecologically critical areas.

Bayer CropScience has presented results of agronomic field trials for FG72 soybean. The results of these field trials demonstrate that there are no differences in agronomic practices between FG72 and conventional soybean. The common agricultural practices that would be carried out in the cultivation FG72 soybean are not expected to deviate from current practices, including the use of EPA-registered pesticides. The product is expected to be deployed on agricultural land currently suitable for production of soybean and replace existing varieties, and is not expected to increase the acreage of soybean production.

There are no proposed major ground disturbances; no new physical destruction or damage to property; no alterations of property, wildlife habitat, or landscapes; and no prescribed sale, lease, or transfer of ownership of any property. This action is limited to a determination of nonregulated status of FG72 soybean. This action would not convert land use to nonagricultural use and, therefore, would have no adverse impact on prime farmland. Standard agricultural practices for land preparation, planting, irrigation, and harvesting of plants would be used on agricultural lands planted to FG72 soybean, including the use of EPA-registered pesticides. The grower's adherence to EPA label use restrictions for all pesticides is expected to mitigate potential impacts to the human environment.

With regard to pesticide use, a determination of nonregulated status of FG72 soybean is likely to result in changes to the use of isoxaflutole on soybean. The potential changes in herbicide use are discussed in Section 4.2.2. Isoxaflutole is currently registered by the EPA as a restricted use pesticide in soybean and corn. APHIS assumes that the EPA label would provide for label use restrictions intended to mitigate potential impacts to the human environment, including potential impacts to unique geographic areas. As noted above, APHIS further assumes that the grower will closely adhere to EPA label use restrictions for all pesticides.

Potential impacts to geographic areas have been considered by the EPA in its evaluation of isoxaflutole. Isoxaflutole is currently under registration review by the EPA (EPA, 2011b). With regard to the current registration, EPA conducted both human and environmental risk assessments. Although some risks were identified, the EPA determined that these risks could be mitigated by implementing label use restrictions (EPA, 1997; EPA, 2011d; EPA, 2011h; EPA, 2012f). Additional details regarding the current status of the EPA registration review for isoxaflutole may be found in Appendix C.

All pesticides distributed or sold in the U.S. are subject to registration by the EPA under authority of FIFRA. Glyphosate was first registered for use by the EPA in 1974, and has been assessed several times since then by the EPA and other Federal Agencies (EPA, 2009e). At present, glyphosate is currently undergoing registration review by the EPA. In 1993, the EPA determined that all currently registered pesticide products containing glyphosate would not pose unreasonable risks or adverse effects to humans or the environment, thus permitting its eligibility for the EPA pesticide reregistration program (EPA, 2009e). A preliminary problem formulation has been conducted as part of the registration review of glyphosate by the EPA, identifying what is currently known and uncertainty regarding the ecological risk, environmental fate, endangered species, and drinking water assessment of glyphosate and its transformation products (EPA, 2009e). EPA produced an estimated timeline for the completion of the glyphosate registration review, with a final decision due in 2015 (EPA, 2009a). Submittals that are relevant to the EPA registration review of glyphosate can be submitted under the docket designation EPA-HQ-2009-0361 at the Regulations.gov website.

Based on these findings, including the assumption that EPA label use instructions are in place to protect unique geographic areas and that those label use instructions are adhered to, a determination of nonregulated status of FG72 soybean is not expected to impact unique characteristics of geographic areas such as park lands, prime farm lands, wetlands, wild and scenic areas, or ecologically critical areas.

7.5 National Historic Preservation Act (NHPA) of 1966 as Amended

The NHPA of 1966 and its implementing regulations (36 CFR 800) require Federal agencies to: 1) determine whether activities they propose constitute "undertakings" that have the potential to cause effects on historic properties and 2) if so, to evaluate the effects of such undertakings on such historic resources and consult with the Advisory Council on Historic Preservation (i.e., State Historic Preservation Office, Tribal Historic Preservation Officers), as appropriate.

APHIS' proposed action, a determination of nonregulated status of FG72 is not expected to adversely impact cultural resources on tribal properties. Any farming activity that may be taken by farmers on tribal lands would only be conducted at the tribe's request; thus, the tribes would have control over any potential conflict with cultural resources on tribal properties.

APHIS' Preferred Alternative would have no impact on districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places, nor would it likely cause any loss or destruction of significant scientific, cultural, or historical resources. This action is limited to a determination of non-regulated status of FG72.

APHIS' proposed action is not an undertaking that may directly or indirectly cause alteration in the character or use of historic properties protected under the NHPA. In general, common agricultural activities conducted under this action do not have the potential to introduce visual, atmospheric, or noise elements to areas in which they are used that could result in effects on the character or use of historic properties. For example, there is potential for increased noise on the use and enjoyment of a historic property during the operation of tractors and other mechanical equipment close to such sites. A built-in mitigating factor for this issue is that virtually all of the methods involved would only have temporary effects on the audible nature of a site and can be ended at any time to restore the audible qualities of such sites to their original condition with no further adverse effects. Additionally, these cultivation practices are already being conducted throughout the soybean production regions. The cultivation of FG72 is not expected to change any of these agronomic practices that would result in an adverse impact under the NHPA.

8 REFERENCES

Coordinated Framework for Regulation of Biotechnology 1986. Pub. L. Stat. June 26.
Statement of Policy: Foods Derived from New Plant Varieties 1992. Pub. L. Stat. May 29.
Glyphosate: Pesticide Tolerances 1997. Pub. L. Stat. Aprill 11.
Mesotrione, Pesticide Tolerances 2009. Pub. L. Stat. December 18.
Isoxaflutole: Pesticide Tolerances 2011. Pub. L. Stat. December 7.
77 FR 41358. 2012.
Endangered Species Protection Program Field Implementation 2005. Pub. L. Stat. November 2.
Al-Kaisi, M; Hanna, M; and Tidman, M (2003) "Crop Rotation Considerations for 2004 Management Season Rotation." Integrated Crop Management. http://www.ipm.iastate.edu/ipm/icm/2003/12-15-2003/croprotation.html >.
Altieri, M (1999) "The ecological role of biodiversity in agroecosystems." *Agriculture, Ecosystems and Environment.* 74 (1-3): p 19-31. http://www.sciencedirect.com/science/article/pii/S0167880999000286 >.
Aneja, V; Schlesinger, W; and Erisman, J (2009) "Effects of Agriculture upon the Air Quality and Climate: Research, Policy, and Regulations." *Environmental Science & Technology.* 43 (12): p 4234-40. Last Accessed: 2011/11/29 < http://dx.doi.org/10.1021/es8024403 >.
AOSCA (2010) "General IP Protocols Standards." The Association of Official Seed Certifying Agencies. http://www.identitypreserved.com/handbook/aosca-general.htm >.
AOSCA (2011) "A Report of the National Soybean Variety Review Board." Association of Seed Certifying Agencies. http://www.aosca.org/VarietyReviewBoards/Soybean/2011SoybeanReport_Final.pdf >.
APAG (2011) "Fatty Acids & Glycerine: Major Production Routes Starting from Vegetable & Animal Oils and Fats." The European Oleochemicals and Allied Products Group. http://www.apag.org/oleo/fats.htm >.
Aref, S and Pike, D (1998) "Midwest Farmers' Perceptions of Crop Pest Infestation." *Agronomy Journal.* 90 (6): p 819-25. https://www.soils.org/publications/aj/abstracts/90/6/819 >.
ASA "2011 Soystats Homepage." American Soybean Association. http://www.soystats.com/2011/ >.
ATTRA (1999) "Sustainable Soil Management." Appropriate Technology Transfer for Rural Areas. http://www.soilandhealth.org/01aglibrary/010117attrasoilmanual/010117attra.html >.
Baker, J; Southard, R; and Mitchell, J (2005) "Agricultural Dust Production in Standard and Conservation Tillage Systems in the San Joaquin Valley." *Journal of Enviromental Quality.* 34 (4): p 1260-69. https://www.soils.org/publications/jeq/abstracts/34/4/1260 >.
Bale, JS; Masters, GJ; Hodkinson, ID; Awmack, C; Bezemer, TM; Brown, VK; Butterfield, J; Buse, A; Coulson, JC; Farrar, J; Good, JEG; Harrington, R; Hartley, S; Jones, TH; Lindroth, RL; Press, MC; Symrnioudis, I; Watt, AD; and Whittaker, JB (2002) "Herbivory in global climate change research: direct effects of rising temperature on insect herbivores." *Global Change Biology.* 8 (1): p 1-16. http://dx.doi.org/10.1046/j.1365-2486.2002.00451.x >.

Barrentine, W (1989) "Minimum Effective Rate of Chlorimuron and Imazaquin Applied to Common Cocklebur (Xanthium strumarium)." *Weed Technology*. 3 (1): p 126-30. http://www.jstor.org/stable/3987133 >.

Barrett, S (1983) "Crop Mimicry in Weeds." *Economic Botany*. 37 p 255-82.

Baucom, R and Holt, J (2009) "Weeds of agricultural importance: Bridging the gap between evolutionary ecology and crop and weed science." *New Phytologist.* (184): p 741-43.

Bayer (2011a) "Balance PRO Herbicide Registration." Bayer CropScience. http://www.epa.gov/pesticides/chem_search/ppls/000264-00600-20111107.pdf >.

Bayer (2011b) "Bayer Balance PRO." Bayer CropScience. http://www.epa.gov/pesticides/chem_search/ppls/000264-00600-20110103.pdf >.

Bayer (2011c) "Petition for the Determination of Nonregulated Status for Event FG72." Submitted by Isabelle S. Coats, Registration Manager. Bayer Crop Science. http://www.aphis.usda.gov/biotechnology/not_reg.html >.

Beckie, HJ (2006) "Herbicide-resistant weeds: Management tactics and practices." *Weed Technology*. 20 (3): p 793-814.

Beckie, HJ and Reboud, X (2009) "Selecting for weed resistance: Herbicide rotation and mixture." *Weed Technology*. 23 (3): p 363-70.

Beltrán, E; Fenet, H; Cooper, J-F; and Coste, C-M (2002) "Fate of Isoxaflutole in Soil under Controlled Conditions." *Journal of Agricultural and Food Chemistry*. 51 (1): p 146-51. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf0207878 >.

Benbrook, C (2009) "Impacts of Genetically Modified Crops on Pesticide Use in the United States: The First Thirteen Years." http://www.organic-center.org/reportfiles/GE13YearsReport.pdf >.

Benbrook, CM (2012) "Impacts of genetically engineered crops on pesticide use in the U.S. -- the first sixteen years." *Environmental Sciences Europe*. 24 (24). http://www.enveurope.com/content/24/1/24 >.

Boethel, D (2004) "Integrated Management of Soybean Insects." *Soybeans: Improvement, Production, and Uses. Third Edition*. Madison, WI: American Society of Agronomy. Crop Science Society of America. Soil Science Society of America. p 853-81.

Bolen, E and Robinson, W (2003) *Wildlife Ecology and Management*. Ed. Edition, 5th. Upper Saddle River: Prentice Hall.

Bonny, S (2011) "Herbicide-tolerant Transgenic Soybean over 15 Years of Cultivation: Pesticide Use, Weed Resistance, and Some Economic Issues. The Case of the USA." *Sustainability*. 3 p 1302-22.

Bradford, K (2006) "Methods to Maintain Genetic Purity of Seed Stocks." Agricultural Biotechnology in California Series Publication 8189. http://ucanr.org/freepubs/docs/8189.pdf >.

Brenner, JK; Paustian, G; Bluhm, J; Cipra, M; Easter, M; Elliott, ET; Kautza, T; Kilian, K; Schuler, J; and Williams, S (2001) "Quantifying the Change in Greenhouse Gas Emissions Due to Natural Resource Conservation Practice Application in Iowa. Final Report to the Iowa Conservation Partnership." Colorado State University Natural Resource Ecology Laboratory and USDA Natural Resources Conservation Service.

Brookes, G and Barfoot, P (2010) "GM Crops: Global Socio-Economic and Environmental Impacts 1996-2008." PG Economics Ltd.

Brookes, G and Barfoot, P (2012a) "Global impact of biotech crops: Environmental effects, 1996–2010." *GM Crops.* 3 (2): p 9. http://www.landesbioscience.com/journals/gmcrops/article/20061/2012GMC0002R.pdf >.
Brookes, G and Barfoot, P (2012b) "GM Crops: Global Socio-economic and Environmental Impacts 1996-2010." PG Economics Ltd, UK.
Brookes, G; Carpenter, JE; and McHughen, A (2012) "A review and assessment of "impact of genetically engineered crops on pesticide use in the US - the first sixteen years: Benbrook C (2012)"." *Environmental Sciences Europe.* 24 (24): p 14.
Cahoon, E (2003) "Genetic enhancement of soybean oil for industrial uses: Prospects and challenges." http://www.aseanfood.info/Articles/11013538.pdf >.
Cargill (2011) "Oils for healthy solutions. Food ingredients. Blends." Cargill. http://www.cargill.com/food/na/en/products/oils-shortenings/oils-for-healthy-solutions/solutions/blends/index.jsp >.
Carpenter, J and Gianessi, L (1999) "Herbicide-Tolerant Soybeans: Why Farmers are Adopting Round-up Ready Varieties." http://agbioforum.org/v2n2/v2n2a02-carpenter.htm >.
Carpenter, J and Gianessi, L (2010) "Economic Impact of Glyphosate-Resistant Weeds." *Glyphosate Resistance in Crops and Weeds*. Hoboken, NJ: John Wiley & Sons, Inc. p 213-33.
Carpenter, JE (2011) "Impacts of GM crops on biodiversity." *GM Crops.* 2 (1): p 1-17.
Caviness, CE (1966) "Estimates of Natural Crosspollination in Jackson Soybeans in Arkansas." *Crop Science.* 6 (2): p 211-12. https://www.crops.org/publications/cs/abstracts/6/2/211 >.
CBD (2010) "The Cartegena Protocol on Biosafety " Convention on Biological Diversity. http://www.cbd.int/biosafety/ >.
CCSP (2009) "Global Climate Change Impacts in the United States." U.S. Global Change Research Program.
Center for Food Safety to: APHIS. (2012). Comment to USDA APHIS on Draft Environmental Assessment and Draft Plant Pest Risk Assessment for "Bayer Petition 09-328-01 Determination of Non-regulated Status of Double Herbicide-tolerant Soybeam (Glycine Max) Event FG72": isoxaflutole- and glyphosate-resistant soybean. Last Accessed: January, 2013 < http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0029-0081 >.
CFIA (1998) "Decision Document 1999-33: Determination of the Safety of Monsanto Canada Inc.'s Roundup ReadyTM Corn(Zea mays L.) Line GA21 " Canadian Food Inspection Agency. http://cera-gmc.org/docs/decdocs/01-290-060.pdf >.
CFIA (2011) "Government of Canada - Biotechnology Notices of Submission." Canadian Food Inspection Agency. http://www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml >.
Clarkson, L (2007) "Statement of the President of Clarkson Grain Co., Inc. Subcommittee on Horticulture and Organic Agriculture—Public Hearing." http://www.google.com/url?sa=t&rct=j&q=witness%20opening%20statements%20house%20committee%20on%20agriculture%20lynn%20clarkson&source=web&cd=4&ved=0CDgQFjAD&url=http%3A%2F%2Fagriculture.house.gov%2Ftestimony%2F110%2Fh70418%2FLClarkson.doc&ei=fwGMT_SbJ6Ge2QWT98DpCQ&usg=AFQjCNFLQonZNOYhlZjsQjhTqj73i9PQlA >.
Coates, I to: Vongpaseuth, Khamkeo. (2012). Personal Communication.

Cook, E; Bartlein, P; Diffenbaugh, N; Seager, R; Shuman, B; Webb, R; Williams, J; and Woodhouse, C (2008) "Hydrological Variability and Change." The U.S. Climate Change Science Program.

CTIC (2008) "2008 Amendment to the National Crop Residue Management Survey Summary." Conservation Technology Information Center. http://www.ctic.purdue.edu/media/pdf/National%20Summary%202008%20(Amendment).pdf >.

CTIC (2010) "Facilitating Conservation Farming Practices and Enhancing Environmental Sustainability with Agricultural Biotechnology." Conservation Technology Information Center. http://www.improveagriculture.com/uploads/files/BiotechFinal2.pdf >.

Culpepper, A; Grey, T; Vencill, W; Kichler, J; Webster, T; Brown, S; York, A; Davis, J; and Hanna, W (2006) "Glyphosate-resistant Palmer (*Amaranthus palmeri*) confirmed in Georgia." *Weed Technology*. 54 p 620-26.

Culpepper, AS; Whitaker, JR; MacRae, A; and York, AC (2008) "Distribution of glyphosate-resistant Palmer Amaranth (*Amaranthus palmeri*) in Georgia and North Carolina during 2005 and 2006." *Journal of Cotton Science.* 12 p 306-10.

Dalley, C; Renner, K; and Kells, J (2001) "Weed Competition in Roundup Ready Soybeans and Corn." http://web1.msue.edu/iac/434/weedcompetitioninroundupreadysoycorn.pdf >.

DATCP (2002) "Final Environmental Impact Statement for the Use of Pesticides Containing Isoxaflutole in Wisconsin." Wisconsin Department of Agriculture, Trade and Consumer Protection Water Quality Section. http://www.midwestadvocates.org/archive/DATCPisoxaflutole/EIS_Final_17.pdf >.

Diggle, AJ; Neve, PB; and Smith, FP (2003) "Herbicides used in combination can reduce the probability of herbicide resistance in finite weed populations." *Weed Research.* 43 (5): p 371-82.

Dill, GM (2005) "Glyphosate-resistant crops: history, status and future." *Pest Management Science.* 61 (3): p 219-24. http://dx.doi.org/10.1002/ps.1008 >.

Dill, GM; CaJacob, CA; and Padgette, SR (2008) "Glyphosate-resistant crops: adoption, use and future considerations." *Pest Management Science.* 64 (4): p 326-31. http://dx.doi.org/10.1002/ps.1501 >.

Doran, JW; Sarrantonio, M; and Liebig, MA (1996) "Soil Health and Sustainability." *Advances in Agronomy*. Academic Press. p 1-54. http://books.google.com/books?hl=en&lr=&id=DWpXP0UKS7kC&oi=fnd&pg=PA1&ots=CcPwqtioKw&sig=0ZdWes87PTmaGeLXOIWrzAuAHVE#v=onepage&q&f=false >.

Duke, SO and Powles, SB (2008) "Glyphosate-Resistant Weeds and Crops." *Pest Management Science.* 64 (4): p 317-18. http://dx.doi.org/10.1002/ps.1561 >.

Duke, SO and Powles, SB (2009) "Glyphosate-resistant crops and weeds: Now and in the future." *AgBioForum.* 12 (3&4): p 346-57.

Dunfield, KE and Germida, JJ (2004) "Impact of genetically modified crops on soil- and plant-associated microbial communities." *J. Environ. Qual.* 33 p 806-15.

EFSA. "Request for Authorization of Herbicide Tolerant Genetically Modified Soybean FG72 for food and feed uses, and import and processing, in accordance with articles 5 and 17 of Regulation (EC) N° 1829/2003 GM Food and GM Feed." European Food Safety Authority, 2011a.

EFSA (2011b) "Request for Authorization of Herbicide Tolerant Genetically Modified Soybean FG72 for Food, Feed Uses, and Import and Processing, in Accordance with Articles 5 and 17 of Regulation (EC) N° 1829/2003 GM Food and GM Feed." European Food and Safety Authority.

EIA (2007) "Biofuels in the US Transportation Sector." http://www.eia.gov/oiaf/analysispaper/biomass.html >.

EPA (1993) "R.E.D. Facts - Glyphosate." Environmental Protection Agency. http://www.epa.gov/oppsrrd1/REDs/factsheets/0178fact.pdf >.

EPA (1997) "Isoxaflutole: Review of Eco-Toxicity Studies for New Chemical Registration." Enviromental Protection Agency. http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-123000_1-Apr-97_059.pdf >.

EPA (1998) "EPA Fact Sheet - Isoxaflutole." Enviromental Protection Agency. http://www.epa.gov/opprd001/factsheets/isoxaflutole.pdf >.

EPA (2000) "Profile of the Agricultural Crop Production Industry." U.S. Environmental Protection Agency-Office of Compliance Sector Notebook Profile. http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/agcrop.pdf >.

EPA (2001) "Drinking Water Assessment for Isoxaflutole." Environmental Protection Agency. http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-123000_undated_001.pdf >.

EPA. "Isoxaflutole Monitoring Data from Missouri: Update on Reservoirs." Environmental Protection Agency, 2002.

EPA (2004) "Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations." Environmental Protection Agency. http://www.epa.gov/oppfead1/endanger/consultation/ecorisk-overview.pdf >.

EPA (2005) "Protecting Water Quality from Agricultural Runoff." Environmental Protection Agency. http://www.epa.gov/owow/NPS/Ag_Runoff_Fact_Sheet.pdf >.

EPA (2007) "Regulatory Impact Analysis: Renewable Fuel Standard Program - Chapter 8 Agricultural Sector Impacts." http://www.epa.gov/otaq/renewablefuels/420r07004chap8.pdf >.

EPA (2008) "Ecological Risk Assessment for Experimental Use Permit (DP Barcode 354510) and Section 3 New Use (DP Barcode 357888) Registrations for use of Mesotrione on Soybeans." Environmental Protection Agency.

EPA (2009a) "Glyphosate Final Work Plan." Environmental Protection Agency.

EPA (2009b) "Mesotrione: Human-Health Risk Assessment for Section 3 New Use on Soybeans." Environmental Protection Agency.

EPA (2009c) "Pesticide Issues in the Works: Pesticide Volatization." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/pesticides/about/intheworks/volatilization.htm >.

EPA (2009d) "Pesticide Spray and Dust Drift." U.S. Environmental Protection Agency. http://www.epa.gov/opp00001/factsheets/spraydrift.htm >.

EPA (2009e) "Registration Review- Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and Its Salts (PC Code

417300, 103601, 103604, 103607, 103608, 103613, 103603, 103605, 128501)." Environmental Protection Agency.
EPA (2010a) "Climate change indicators in the United States." Environmental Protection Agency. http://www.epa.gov/climatechange/indicators/pdfs/ClimateIndicators_full.pdf >.
EPA (2010b) "Draft 2010 Inventory of Greenhouse Gas Emissions and Sinks Executive Summary." Enviromental Protection Agency. http://www.epa.gov/climatechange/emissions/ >.
EPA (2010c) "Ecological Risk Assessment Addressing the "Crop Destruct" Experimental Use Permit (EUP) for Isoxaflutole and its End-product Balance PRO Herbicide for use on Selected Soybean Varieties."
EPA (2010d) "Ecological Risk Assessment for the Isoxalfutole Proposed Section 3 Registration for Use on Soybeand and on Corn in Five Additional Southern States (South Carolina, Georgia, Alabama, Mississippi, and Louisiana)."
EPA (2010e) "EPA Registration Division Company Notice of Filing for Pesticide Petition Published in the Federal Register." Enviromental Protection Agency.
EPA (2010f) "Inventory of US Greenhouse Gas Emissions and Sinks: 1990 - 2008." Environmental Protection Agency. http://www.epa.gov/climatechange/emissions/downloads10/508_Complete_GHG_1990_2008.pdf >.
EPA (2010g) "A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: Field Volatilization of Conventional Pesticides." U.S. Environmental Protection Agency. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037 >.
EPA (2011a) "Basic Information About ESPP." Environmental Protection Agency. http://www.epa.gov/oppfead1/endanger/basic-info.htm >.
EPA (2011b) "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency.
EPA. "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency, 2011c.
EPA (2011d) "Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment."
EPA. "Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment." Environmental Protection Agency, 2011e.
EPA (2011f) "Pesticide Registration Program." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/pesticides/factsheets/registration.htm#priorities >.
EPA. "Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole." Washington DC: Environmental Protection Agency, 2011g.
EPA (2011h) "Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole." Environmental Protection Agency.
EPA (2012a) "Basic Principles of the Worker Protection Standard." EPA. Last Accessed: April 18, 2013 < http://www.epa.gov/oppfead1/safety/workers/principl.htm >.

EPA (2012b) "Chapter 6: Agriculture." *Inventory of U.S. Greenhouse Gas Emissions and Sinks: 1990-2010*. Washington, DC: U.S. Environmental Protection Agency. p 6-1 through 6-41. http://www.epa.gov/climatechange/ghgemissions/usinventoryreport.html >.
EPA (2012c) "Index to Pesticide Chemical Names, Part 180 Tolerance Information, and Food and Feed Commodities (by Commodity)." Environmental Protection Agency. http://www.epa.gov/opp00001/regulating/tolerances-commodity.pdf >.
EPA (2012d) "Pesticide Tolerances " Environmental Protection Agency. http://www.epa.gov/pesticides/regulating/tolerances.htm >.
EPA (2012e) "Pesticides: Endangered Species Protection Program." Environmental Protection Agency. http://www.epa.gov/oppfead1/endanger/ >.
EPA (2012f) "Restricted-Use Pesticides." Environmental Protection Agency. http://www.epa.gov/oppfead1/safety/applicators/restrict.htm >.
EPA "EPA Pesticide Search." Environmental Protection Agency. Last Accessed: January, 2013 < http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:1:51296093318144 >.
EPA (2013b) "Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/oecaagct/lfra.html >.
EPA "National Water Quality Assessment and Total Maximum Daily Load Database " EPA. Last Accessed: 15 April 2013 < http://www.epa.gov/waters/ir/ >.
EPA (2013d) "Pesticide Registration." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/pesticides/factsheets/registration.htm >.
EPA (2013e) "Registering Pesticides." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/opp00001/regulating/registering/ >.
EPA (2013f) "Setting Tolerances for Pesticide Residues in Food." Environmental Protection Agency. Last Accessed: January, 2013 < http://www.epa.gov/opp00001/factsheets/stprf.htm >.
EPA (2013g) "State Registration of Pesticides." EPA. Last Accessed: April 11, 2013 < http://www.epa.gov/pesticides/regulating/registering/index.htm#state >.
European Commission (2003) "Review report for the active substance isoxaflutole, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 April 2003 in view of the inclusion of isoxaflutolein Annex I of Directive 91/414/EEC."
FAPRI (2012) "U.S. and World Agricultural Outlook." Food and Agricultural Policy Research Institute. http://www.fapri.iastate.edu/outlook/2012/tables/3-Oil.pdf >.
Faust, M (2002) "New feeds from genetically modified plants: The US approach to safety for animals and the food chain." *Livestock Production Science.* 74 (3): p 239-54.
FDA (2012a) "Completed Consultations on Bioengineered Foods BNF No. 122." FDA. http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=bioListing&id=89 >.
FDA (2012b) "Plant Biotechnology for Food and Feed." U.S. Food and Drug Administration. http://www.fda.gov/Food/Biotechnology/default.htm >.
Felsot, A; Unsworth, J; Linders, J; Roberts, G; Rautman, D; Harris, C; and Carazo, E (2011) "Agrochemical spray drift; assessment and mitigation—A review." *Journal of Environmental Science and Health, Part B.* 46 (1): p 1-23. http://www.informaworld.com/smpp/title~content=t713597269 >.
Fernandez-Cornejo, J; Klotz-Ingram, C; Heimlich, R; Soule, M; McBridge, W; and Jans, S (2003) "Economic and Environmental Impacts of Herbicide Tolerant and Insect Resistant

Crops in the United States." *The Economic and Enviromental Impacts of Agbiotech: A Global Perspective*. New York, NY: Kluwer Academic/Plenum Publishers. p 63-88.
Fernandez-Cornejo, J; Klotz-Ingram, C; and Jans, S (2002) "Farm-Level Effects of Adopting Herbicide-Tolerant Soybeans in the U.S.A." *Journal of Agriculture and Applied Economics.* 34 (1): p 149-63.
Fernandez-Cornejo, J and McBride, W (2000) "Genetically Engineered Crops for Pest Management in US Agriculture: Farm-Level Effects." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/publications/aer786/aer786.pdf >.
Fernandez-Cornejo, J; Nehring, R; Sinha, EN; Grube, A; and Vialou, A (2009) "Assessing recent trends in pesticide use in U. S. agriculture." *Meeting of the AAEA*. http://ageconsearch.umn.edu/bitstream/49271/2/Fernandez-Cornejo%20et%20al%20%20-%20AAEA%202009%20-%20Selected%20Paper%20-%20%20April%2019.pdf >.
Ferrell, JA; MacDonald, GE; and Leon, R (2012) "Weed Management in Soybeans." University of Florida. Last Accessed: April 18, 2013 < http://edis.ifas.ufl.edu/pdffiles/WG/WG01000.pdf >.
Flachowsky, G; Chesson, A; and Aulrich, K (2005) "Animal nutrition with feeds from genetically modified plants." *Archives of Animal Nutrition.* 59 (1): p 1-40.
Frisvold, GB; Hurley, TM; and Mitchell, PD (2009) "Adoption of best management practices to control weed resistance by corn, cotton, and soybean growers." *AgBioForum.* 12 p 370-81.
FSANZ (2001) "Food Derived from Glyphostate-tolerant Corn Line GA21 - A Safety Assessment." Food Standards Australia New Zealand. http://www.foodstandards.gov.au/_srcfiles/TR7.pdf >.
FSANZ (2011a) "Application A1051. Food Derived from Herbicide-Tolerant Soybean Line FG72 Approval Report." Food Standards Australia New Zealand. http://www.foodstandards.gov.au/_srcfiles/A1051%20GM%20Soy%20FG72%20AppR%20FINAL.pdf >.
FSANZ (2011b) "Supporting Document 1 - Application A1051 - Food Derived from Herbicide-Tolertant Soybean Line FG72 - Safety Assessment Report - Summary and Conclusions." Food Standards Australia New Zealand. http://www.foodstandards.gov.au/_srcfiles/A1051%20GM%20Soy%20FG72%20AR%20SD1%20Safety%20Assess.pdf >.
Galle, A; Linz, G; Homan, H; and Bleier, W (2009) "Avian Use of Harvested Crop Fields in North Dakota During Spring Migration." *Western North American Naturalist.* 69 (4): p 491-500. Last Accessed: 2011/11/29 < http://dx.doi.org/10.3398/064.069.0409 >.
Gamble, L; Johnson, K; Linder, G; and Harrahy, E (2002) "The migratory bird treaty act and concerns for nontarget birds relative to spring baiting with DRC-1339." Bismarck, North Dakota.
Garbeva, P; van Veen, J; and van Elsas, J (2004) "Microbial Diversity in Soil: Selection of Microbial Populations by Plant and Soil Type and Implications for Disease Suppressiveness." *Annual Review of Phytopathology.* 42 (1): p 243-70. http://www.annualreviews.org/doi/abs/10.1146/annurev.phyto.42.012604.135455 >.
Gianessi, L and Reigner, N (2007) "The value of herbicides in U.S. crop production." *Weed Technology.* 21 p 559-66.

Gianessi, LP (2008) "Economic impacts of glyphosate-resistant crops." *Pest Management Science.* 64 (4): p 346-52. http://dx.doi.org/10.1002/ps.1490 >.

Gibson, KD; Johnson, WG; and Hillger, DE (2005) "Farmer perceptions of problematic corn and soybean weeds in Indiana." *Weed Technology.* 19 p 1065-70.

GINA (2011) "Livestock - #1 Customer for Soybean Meal." Growing in Agriculture. http://www.growinginagriculture.com/ >.

Givens, W; Shaw, D; Kruger, G; Johnson, W; Weller, S; Young, B; Wilson, R; Owen, M; and Jordan, D (2009) "Survey of Tillage Trends Following The Adoption of Glyphosate-Resistant Crops." *Weed Technology.* 23 (1): p 150-55. Last Accessed: 2011/11/22 < http://dx.doi.org/10.1614/WT-08-038.1 >.

Grandy, AS; Loecke, TD; Parr, S; and Robertson, GP (2006) "Long-Term Trends in Nitrous Oxide Emissions, Soil Nitrogen, and Crop Yields of Till and No-Till Cropping Systems." *Journal of Enviromental Quality.* 35 (4): p 1487-95. https://www.soils.org/publications/jeq/abstracts/35/4/1487 >.

Green, JM and Owen, MD (2011) "Herbicide-resistant crops: Utilities and limitations for herbicide-resistant weed management." *Journal of Agricultural and Food Chemistry.* 59 p 5819-29.

Gregorich, EG; Rochette, P; Hopkins, DW; McKim, UF; and St-Georges, P (2006) "Tillage-induced environmental conditions in soil and substrate limitation determine biogenic gas production." *Soil Biology and Biochemistry.* 38 (9): p 2614-28. http://www.sciencedirect.com/science/article/pii/S0038071706001969 >.

Gregorich, EG; Rochette, P; VandenBygaart, AJ; and Angers, DA (2005) "Greenhouse gas contributions of agricultural soils and potential mitigation practices in Eastern Canada." *Soil and Tillage Research.* 83 (1): p 53-72. http://www.sciencedirect.com/science/article/pii/S0167198705000371 >.

Gunsolus, J (2012) "Weed Control in Soybean." Last Accessed: January, 2013 < http://appliedweeds.cfans.umn.edu/weedbull/Soybeans.pdf >.

Hahn, L; Theller, L; Reimer, A; and Engel, B. "Pesticides sensitive crops and habitats: Registry implementation results." Washington D.C.: American Chemical Society, 2011.

Harlan, J (1975) "Our Vanishing Genetic Resources." *Science.* 188 (4188): p 617-21. http://www.sciencemag.org/content/188/4188/617.short >.

Hart, M; Powell, J; Gulden, R; Dunfield, K; Pauls, K; Swanton, C; Klironomos, J; Antunes, P; Koch, A; and Trevors, J (2009) "Separating the effect of crop from herbicide on soil microbial communities in glyphosate-resistant corn." *Pedobiologia.* 52 p 253-62.

Hartnell, F (2010) "Do Genetically Engineered Crops make Economic Sense." *Southwest Nutrition and Management Conference.*

Hausman, NE; Singh, S; Tranel, PJ; Riechers, DE; Kaundun, SS; Polge, ND; Thomas, DA; and Hager, AG (2011) "Resistance to HPPD-inhibiting herbicides in a population of waterhemp Amaranthus tuberculatus from Illinois, United States." *Pest Management Science.* 67 (3): p 258-61. http://www.ingentaconnect.com/content/jws/ps/2011/00000067/00000003/art00002 http://dx.doi.org/10.1002/ps.2100 >.

Heap, I (2011) "The International Survey of Herbicide Resistant Weeds - 4-HPPD Inhibitors (F2/F27) Resistant Weeds by Species and Country." Weed Science. http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=10 >.

Heap, I (2013) "International Survey of Herbicide Resistant Weeds." Weed Science. Last Accessed: January, 2013 < http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go >.

Helsel, Z and Minor, H (1993) "Soybean Production in Missouri." University of Missouri Extension. http://extension.missouri.edu/publications/DisplayPrinterFriendlyPub.aspx?P=G4410 >.

Hoeft, R; Nafziger, E; Johnson, R; and Aldrich, S (2000) *Modern Corn and Soybean Production*. Champaign, IL: MCSP Publications.

Holland, J (2004) "The Environmental Consequences of Adopting Conservation Tillage in Europe: Reviewing the Evidence." *Agriculture, Ecosystems, and Environment.* 103 (1): p 1-25. http://www.sciencedirect.com/science/article/pii/S0167880904000593 >.

HRAC (2012) "HRAC website." Herbicide Resistance Action Committee. http://hracglobal.com/ >.

HRAC (2013) "Guideline to the Management of Herbicide Resistance." Herbicide Resistance Action Committee, Bayer CropScience AG. http://www.hracglobal.com/Publications/ManagementofHerbicideResistance.aspx >.

Hubbard, K (2008) "A Guide to Genetically Modified Alfalfa." Western Organization of Resource Councils. <http://www.worc.org/userfiles/file/Guide_%20to_%20GM_%20Alfafa_%20v2.pdf> >.

Hurley, T; Mitchell, P; and Frisvold, G (2009) "Weed Management Costs, Weed Best Management Practices, and the RoundUp Ready® Weed Management Program." *AgBioForum.* 12 (No. 3 & 4): p 281 - 90. http://www.agbioforum.org/v12n34/v12n34a04-mitchell.pdf >.

Ian Heap to: Kham Vongpaseuth. (2012). Estimation of Glyphosate-resistant weeds in States that Grow Soybean and Where Isoxaflutole is Registered for Use on Soybean.

Iowa State University (No Date) "Biological Agents - The European Corn Borer." http://www.ent.iastate.edu/pest/cornborer/manage/agents >.

IPPC (2007) "Climate Change 2007: The Physical Science Basis." Intergovernmental Panel on Climate Change. http://www.ipcc.ch/publications_and_data/publications_ipcc_fourth_assessment_report_wg1_report_the_physical_science_basis.htm >.

IPPC (2010) "Official web site for the International Plant Protection Convention: International Phytosanitary Portal " International Plant Protection Convention. https://www.ippc.int/IPP/En/default.jsp >.

Jasinski, JR; Eisley, JB; Young, CE; Kovach, J; and Willson, H (2003) "Select nontarget arthropod abundance in transgenic and nontransgenic field crops in Ohio." *Environmental Entomology.* 32 (2): p 407-13.

Johnsen, AR; Wick, LY; and Harms, H (2005) "Principles of microbial PAH-degradation in soil." *Environmental Pollution.* 133 (1): p 71-84. http://www.sciencedirect.com/science/article/pii/S0269749104001587 >.

Johnson, B; Marquardt, P; and Nice, G. "Volunteer Corn Competition and Control in Soybeans." Issue 14 ed: Entomology Extension, Purdue University, 2010. 14 of *Pest & Crop Newsletter*. http://extension.entm.purdue.edu/pestcrop/2010/issue14/index.html#volunteer.

Johnson, WG; Owen, MDK; Kruger, GR; Young, BG; Shaw, DR; Wilson, RG; Wilcut, JW; Jordan, DL; and Weller, SC (2009) "U.S. Farmer Awareness of Glyphosate-Resistant Weeds and Resistance Management Strategies." *Weed Technology.* 23 (2): p 308-12. Last Accessed: 2012/01/11 < http://dx.doi.org/10.1614/WT-08-181.1 >.

Jordan, N; Mortensen, DA; Prenzlow, DM; and Cox, KC (1995) "Simulation analysis of crop rotation effects on weed seedbanks." *American Journal of Botany.* 82 (3): p 390-98.

Jordan, T; Nice, G; Johnson, B; and Bauman, T (2009) "Reducing Spray Drift from Glyphosate and Growth Regulator Herbicide Drift Caution." www.btny.purdue.edu/weedscience >.

Karl, T; Meehl, G; Miller, C; Hassol, S; Waple, A; and Murray, W (2008) "Weather and Climate Extremes in a Changing Climate - Regions of Focus: North America, Hawaii, Caribbean, and U.S. Pacific Islands." The U.S. Climate Change Science Program. http://www.climatescience.gov/Library/sap/sap3-3/final-report/ >.

Kladivko, EJ (2001) "Tillage systems and soil ecology." *Soil and Tillage Research.* 61 (1–2): p 61-76. http://www.sciencedirect.com/science/article/pii/S0167198701001799 >.

Krapu, G; Brandt, D; and Cox, R (2004) "Less Waste Corn, More Land in Soybeans, and the Switch to Genetically Modified Crops: Trends with Important Implications for Wildlife Management." USGS Northern Prairie Wildlife Research Center. http://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1065&context=usgsnpwrc >.

KSU. (1997). ed.^eds. *Soybean Production Handbook*. Kansas State University, Agricultural Experiment Station and Cooperative Extension Service. Print.

Lal, R and Bruce, J (1999) "The potential of world cropland soils to sequester C and mitigate the greenhouse effect." *Environmental Science and Policy.* 2 (2): p 177-85. http://www.ingentaconnect.com/content/els/14629011/1999/00000002/00000002/art00012
http://dx.doi.org/10.1016/S1462-9011(99)00012-X >.

Landis, DA; Menalled, FD; Costamagna, AC; and Wilkinson, TK (2005) "Manipulating plant resources to enhance beneficial arthropods in agricultural landscapes." *Weed Science.* 53 p 902-08.

Loux, MM; Doohan, D; and Dobbels, AF (2012) "Weed Control Guide for Ohio and Indiana."

Lovett, S; Price, P; and Lovett, J (2003) "Managing Riparian Lands in the Cotton Industry." Cotton Research and Development Corporation. http://www.cottoncrc.org.au/catchments/Publications/Rivers/Managing_Riparian_Lands >.

Lubowski, R; Vesterby, M; Bucholtz, S; Baez, A; and Roberts, M (2002) "Major Uses of Land in the United States, 2002." Enviromental Protection Agency. http://www.ers.usda.gov/publications/EIB14/eib14a.pdf >.

Lupwayi, NZ; Rice, WA; and Clayton, GW (1998) "Soil microbial diversity and community structure under wheat as influenced by tillage and crop rotation." *Soil Biology and Biochemistry.* 30 (13): p 1733-41. http://www.sciencedirect.com/science/article/pii/S003807179800025X >.

MacGowan, B; Humberg, L; Beasley, J; DeVault, T; Retamosa, M; and Rhodes, O (2006) "Corn and Soybean Crop Depredation by Wildlife." Purdue Extension, Department of Forestry and Natural Resources. http://www.ces.purdue.edu/extmedia/FNR/FNR-265-W.pdf >.

Marshall, EJP; Brown, VK; Boatman, ND; Lutman, PJW; Squire, GR; and Ward, LK (2002) "The role of weeds in supporting biological diversity within crop fields." *Weed Research.* 43 p 77-89.
Maurhofer, M; Hase, C; Meuwly, P; Metraux, JP; and Defago, G (1994) "Induction of systemic resistance of tobacco to tobacco necrosis virus by the root-colonizing Pseudomonas fluorescens strain CHA0: influence of the gacA gene and of pyoverdine production." *Phytopathology.* 84 (2): p 139-46. http://ukpmc.ac.uk/abstract/AGR/IND20400182 >.
McKellar, RC (1982) "Factors influencing the production of extracellular proteinase by Pseudomonas fluorescens*." *Journal of Applied Microbiology.* 53 (3): p 305-16. http://dx.doi.org/10.1111/j.1365-2672.1982.tb01276.x >.
Mensah, E (2007) *Economics of Technology Adoption: A Simple Approach*. Sarrbruken, Germany: VDM Verlag.
Monsanto (2010) "Roundup Power Max Herbicide Specimen Label." Monsanto Company. http://www.cdms.net/LDat/ld8CC045.pdf >.
Monsanto (2012) "Petition for the Determination of Nonregulated Status for Dicamba-Tolerant Soybean MON 87708." Submitted by Rhonda M. Mannion, Registration Manager. The Monsanto Company. St. Louis, MO. Last Accessed: January 2013 < http://www.aphis.usda.gov/brs/aphisdocs/10_18801p.pdf >.
Montague, K. (2012). Personal Communication.
Mortensen, DA; Egan, JF; Maxwell, BD; Ryan, MR; and Smith, RG (2012) "Navigating a Critical Juncture for Sustainable Weed Management." *BioScience.* 62 (1): p 75-84. Last Accessed: 2012/03/14 < http://www.bioone.org/doi/abs/10.1525/bio.2012.62.1.12 >.
MSU Extension Service (Undated) "Ecology and Management of the Louisiana Black Bear." http://icwdm.org/Publications/pdf/Bears/bearsMSU.pdf >.
Nandula, V (2010) *Glyphosate Resistance in Crops and Weeds*. Ed. Nandula, VK. Hoboken, NJ: John Wiley & Sons, Inc.
NAPPO (2009) "NAPPO approved standards " http://www.nappo.org/Standards/Std-e.html >.
NBII (2010) "United States Regulatory Agencies Unified Biotechnology Website " http://usbiotechreg.nbii.gov/ >.
NCAT (2003) "NCAT's Organic Crops Workbook: A Guide to Sustainable and Allowed Practices." National Center for Appropriate Technology.
Neve, PB; Norsworthy, JK; Smith, KL; and Zelaya, IA (2011) "Modeling Glyphosate Resistance Management Strategies for Palmer Amaranth (Amaranthus palmeri) in Cotton." *Weed Technology.* 25 (3): p 9. http://www.bioone.org/doi/full/10.1614/WT-D-10-00171.1 >.
Non-GMO-Project (2010) "Non-GMO Project Working Standard." http://www.nongmoproject.org/wp-content/uploads/2009/06/NGP-Standard-v7.pdf >.
Norsworthy, JK; Ward, SM; Shaw, DR; Llewellyn, RS; Nichols, RL; Webster, TM; Bradley, KW; Frisvold, G; Powles, SB; Burgos, NR; Witt, WW; and Barrett, M (2012) "Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations." *Weed Science.* 60 (sp1): p 31-62.
NPIC (2008) "Signal Words: Topic Fact Sheet." National Pesticide Information Center. http://npic.orst.edu/factsheets/signalwords.pdf >.
NRC (2004) *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*. Washington, D.C.: National Resource Council - The National Academies Press.

NRC (2010a) "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States." National Academies Press.
NRC. "The Impact of Genetically Engineered Crops on Farm Sustainability in the United States.". Washington DC: National Academies Press, 2010b.
NSRL (2011) "National Soybean Research Laboratory - Soybean Production Basics." National Soybean Research Laboratory. http://www.nsrl.illinois.edu/general/soyprod.html >.
NSRL (2013) "Soybean Production Basics." National Soybean Research Laboratory. Last Accessed: January, 2013 < http://www.nsrl.uiuc.edu/aboutsoy/production02.html >.
NY State IPM Program (2012) "A Method to Measure the Environmental Impact of Pesticides." Cornell Cooperative Extension. http://nysipm.cornell.edu/publications/eiq/equation.asp#table2 >.
O'Brian, D (2010) "U.S. Crop Acreage Trends and Soybean/Corn Price Ratios." Kansas State Research and Extension. http://www.agmanager.info/marketing/outlook/newletters/archives/GRAIN-OUTLOOK_12-10-10.pdf >.
OECD (1993) "Safety considerations for biotechnology: Scale-up of crop plants." Last Accessed: January 9, 2009 < www.biosafety.be/CU/BSL_Ressources/PDF/M00034525.pdf >.
OECD (2000) "Consensus document on the biology of *Glycine max* (L.) Merr. (Soybean). Series on harmonization of regulatory oversight in biotechnology, No. 15." http://www.olis.oecd.org/olis >.
OECD (2001) "Consensus Document on Compositional Considerations for New Varieties of Soybeans: Key Food and Feed Nutrients and Anti-nutrients." Organisation for Economic Co-operation and Development. http://www.oecd.org/dataoecd/15/60/46815135.pdf >.
OECD (2010) "Consensus Document on the Biology of Glycine Max (L.) Merr. (Soybean)." Organisation for Economic Co-operation and Development. http://www.oecd.org/dataoecd/16/56/46815668.pdf >.
Owen, M (2010) "Herbicide-Resistant Weeds in Genetically Engineered Crops - Statement of Micheal DK Owen, PhD." National Academies of Science. http://www7.nationalacademies.org/ocga/testimony/t_Herbicide_Resistant_Weeds_in_GE_Crops.asp >.
Owen, M and Zelaya, I (2005) "Herbicide-resistant crops and weed resistance to herbicides " *Pest Management Science.* 61 p 301-11.
Owen, MD; Young, BG; Shaw, DR; Wilson, RG; Jordan, DL; Dixon, PM; and Weller, SC (2011a) "Benchmark study on glyphosate-resistant crop systems in the United States. Part 2: Perspectives." *Pest Management Science.* 67 (7): p 747-57. http://www.ncbi.nlm.nih.gov/pubmed/21452168 >.
Owen, MDK (2008) "Weed species shifts in glyphosate-resistant crops." *Pest Management Science.* 64 p 377-87.
Owen, MDK (2011) "Weed resistance development and management in herbicide-tolerant crops: Experiences from the USA." *Journal of Consumer Protection and Food Safety.* 6 (1): p 85-89.
Owen, MDK; Young, BG; Shaw, DR; Wilson, RG; Jordan, DL; Dixon, PM; and Weller, SC (2011b) "Benchmark study on glyphosate-resistant crop systems in the United States. Part 2: Perspectives." *Pest Management Science.* 67 p 747–57.

Owen, MDK; Young, BG; Shaw, DR; Wilson, RG; Jordan, DL; Dixon, PM; and Weller, SC (2011c) "Benchmark study on glyphosate-resistant crop systems in the United States. Part 2: Perspectives." *Pest Management Science.* 67 (7): p 747-57. http://dx.doi.org/10.1002/ps.2159 >.

Palmer, W; Bromley, P; and Anderson, J (2010) "Pesticides and Wildlife - Soybeans." http://ipm.ncsu.edu/wildlife/soybeans_wildlife.html >.

Papiernik, SK; Yates, SR; Koskinen, WC; and Barber, B (2007) "Processes Affecting the Dissipation of the Herbicide Isoxaflutole and Its Diketonitrile Metabolite in Agricultural Soils under Field Conditions." *Journal of Agricultural and Food Chemistry.* 55 (21): p 8630-39. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf071256s >.

Paustian, K; Brenner, JK; Cipra, J; Easter, M; Killian, K; Williams, S; Asell, L; Bluhm, G; and Kautza, T. "Findings of the Iowa Carbon Storage Project." NREL, Colorado State University; USDA-NRCS, Iowa Department of Natural Resources; and Soil and Water Conservation Society, 2000.

Penn State Extension (2011) "Soybean Insect Pests." Penn State College of Agricultural Sciences. http://extension.psu.edu/agronomy-guide/pm/sec4/sec43a >.

Peterson, D; Olson, B; Al-Khatib, K; Currie, R; Dille, JA; Falk, J; Geier, P; Regehr, D; Stahlman, P; and Thompson, C (2007) "Glyphosate Stewardship: Optimizing and Preserving Glyphosate Performance." Kansas State University, Agricultural Experiment Station and Cooperative Extension Service.

Pierce II, RA; White, B; Jones-Ferrand, DT; Dalley, TV; and Carpenter, B (2008) "Field Borders for Agronomic, Economic and Wildlife Benefits." University of Missouri Extension. http://extension.missouri.edu/p/G9421 >.

Plant and Soil Sciences eLibrary (2013) "The Flower and Sexual Reproduction." Plant and Soil Sciences eLibrary. Last Accessed: January, 2013 < http://passel.unl.edu/pages/informationmodule.php?idinformationmodule=1087230040&topicorder=2&maxto=9 >.

Poole, T (2004) "Crop Rotation." University of Maryland - Maryland Cooperative Extension. Last Accessed: December, 2012 < http://extension.umd.edu/publications/pdfs/fs784.pdf >.

Potter, KN; Torbert, HA; Jones, OR; Matocha, JE; Morrison Jr, JE; and Unger, PW (1998) "Distribution and amount of soil organic C in long-term management systems in Texas." *Soil and Tillage Research.* 47 (3-4): p 309-21. http://www.sciencedirect.com/science/article/pii/S0167198798001196 >.

Powles, SB (2008) "Evolution in action: Glyphosate-resistant weeds threaten world crops." *Outlooks on Pest Management.* 12 p 256-59.

Powles, SB and Preston, C (2009) "Herbicide Cross Resistance and Multiple Resistance in Plants." Herbicide Resistance Action Committee. http://www.hracglobal.com/Publications/HerbicideCrossResistanceandMultipleResistance/tabid/224/Default.aspx >.

Powles, SB; Preston, C; Bryan, IB; and Jutsum, AR (1996) "Herbicide resistance: Impact and management." *Advances in Agronomy*. San Diego, California: Academic Press. p 57-93.

Powles, SB and Yu, Q (2010) "Evolution in Action: Plants Resistant to Herbicides." *Annual Review of Plant Biology.* 61 p 317-47. http://www.annualreviews.org/doi/pdf/10.1146/annurev-arplant-042809-112119 >.

Prather, TS; Ditomaso, JM; and Holt, JS (2000) "Herbicide resistance: Definition and management strategies (Publication 8012)." University of California, Division of Agriculture and Natural Resources. http://anrcatalog.ucdavis.edu/pdf/8012.pdf >.
Price, AJ; Balkcom, KS; Culpepper, SA; Kelton, JA; Nichols, RL; and Schomberg, H (2011) "Glyphosate-resistant Palmer amaranth: A threat to conservation tillage." *Journal of Soil and Water Conservation.* 66 (4): p 265-75.
Prince, JM; Shaw, DR; Givens, WA; Owen, MDK; Weller, SC; Young, BG; Wilson, RG; and Jordan, DL. *Benchmark study: IV. Survey of grower practices for managing glyphosate-resistant weed populations*. Weed Technology.
Purdue (2012) "Corn & Soybean Field Guide - 2012 Edition." Purdue University. http://www3.ag.purdue.edu/agry/dtc/Pages/default.aspx >.
Ramanarayanan, T; Narasimhan, B; and Srinivasan, R (2005) "Characterization of Fate and Transport of Isoxaflutole, a Soil-Applied Corn Herbicide, in Surface Water Using a Watershed Model." *Journal of Agricultural and Food Chemistry.* 53 (22): p 8848-58. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf0508596 >.
Raper, C and Kramer, P (1987) "Stress Physiology." *Soybean: Improvement, Production, and Uses*. Madison, WI: Agronomy Monograph 16. p 589-641.
Ray, vD; Kilen, TC; Abel, vA; and Parisv, RL (2003) "Soybean natural cross-pollination rates under field conditions." *Environmental Biosafety Research.* 2 (02): p 133-38. Last Accessed: 2003 < http://dx.doi.org/10.1051/ebr:2003005 >.
Rector, RJ; Regehr, DL; Barnes, PL; and Loughin, TM (2003) "Atrazine, S-metolachlor, and isoxaflutole loss in runoff as affected by rainfall and management." *Weed Science.* 51 (5): p 810-16. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1614/2002-07 >.
Reddy, K and Norsworthy, J (2010) "Glyphosate-Resistant Crop Production Systems: Impact on Weed Species Shifts." *Glyphosate Resistance in Crops and Weeds*. Hoboken, NJ: John Wiley & Sons, Inc. p 213-33.
RedEagle (2012) "Acifluorfen 2 Label." Last Accessed: April 18, 2013 < http://www.agrian.com/pdfs/RedEagle_Acifluorfen_2_Label.pdf >.
Rice, PJ; Koskinen, WC; and Carrizosa, MJ (2004) "Effect of Soil Properties on the Degradation of Isoxaflutole and the Sorption−Desorption of Isoxaflutole and Its Diketonitrile Degradate." *Journal of Agricultural and Food Chemistry.* 52 (25): p 7621-27. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf049914l >.
Robertson, GP and Swinton, SM (2005) "Reconciling agricultural productivity and environmental integrity: A grand challenge for agriculture." *Frontiers in Agriculture and the Environment.* 3 (1): p 38-46.
Rochette, P; Angers, DA; Chantigny, MH; and Bertrand, N (2008) "Nitrous Oxide Emissions Respond Differently to No-Till in a Loam and a Heavy Clay Soil." *Soil Science Society of America.* 72 (5): p 1363-69. https://www.crops.org/publications/sssaj/abstracts/72/5/1363 >.
Ronald, P and Fouce, B (2006) "Genetic Engineering and Organic Production Systems." http://ucanr.org/freepubs/docs/8188.pdf >.
Ronald, P and Fouche, B (2006) "Genetic Engineering and Organic Production Systems." http://ucanr.org/freepubs/docs/8188.pdf >.
Rosenzweig, C; Iglesias, A; Yang, XB; Epstein, PR; and Chivian, E (2001) "Climate change and extreme weather events: Implications for food production, plant diseases, and pests."

Global Change and Human Health. 2 (2): p 90-104. http://dx.doi.org/10.1023/A:1015086831467 >.
Ross, MA and Childs, DJ (2011) "Herbicide Mode-of-Action Summary." Cooperative Extension Service, Perdue University. http://www.extension.purdue.edu/extmedia/WS/WS-23-W.html >.
Rouquié, D; Capt, A; Eby, WH; Sekar, V; and Hérouet-Guicheney, C (2010) "Investigation of endogenous soybean food allergens by using a 2-dimensional gel electrophoresis approach." *Regulatory Toxicology and Pharmacology.* 58 (3, Supplement): p S47-S53. http://www.sciencedirect.com/science/article/pii/S0273230010001753 >.
Ruhl, G (2012) "Crop Diseases in Corn, Soybean, and Wheat." Department of Botany and Plant Pathology, Purdue University. http://www.btny.purdue.edu/extension/pathology/cropdiseases/soybean/Soybean.html >.
Sandell, L; Bernards, M; Wilson, R; and Klein, R. "Glyphosate-resistant Weeds and Volunteer Crop Management." 2009. 6.
Sandretto, C and Payne, J (2006) "Soil Management and Conservation." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/publications/arei/eib16/eib16_4-2.pdf >.
Sanger (2012) "Pseudomonas." Sanger Institute. http://www.sanger.ac.uk/resources/downloads/bacteria/pseudomonas.html >.
SCF (2002) "Opinion of the Scientific Committee on Food on the safety assessment of the genetically modified maize line GA21, with tolerance to the herbicide glyphosate." Scientific Committee on Food/European Commission/Health & Consumer Protection Directorate-General. http://cera-gmc.org/docs/decdocs/06-031-001.pdf >.
Schmidhuber, J and Tubiello, FN (2007) "Global food security under climate change." *Proceedings of the National Academy of Sciences.* 104 (50): p 19703-08. http://www.pnas.org/content/104/50/19703.abstract >.
Scott, BA and VanGessel, MJ (2007) "Delaware soybean grower survey on glyphosate-resistant horseweed (Conyza canadensis)." *Weed Science.* 21 (1): p 270-74.
Scribner, EA; Meyer, MT; and Kalkhoff, SJ (2006) "Occurrence of Isoxaflutole, Acetamide, and Triazine Herbicides and their Degradation Products in 10 Iowa Rivers Draining to the Mississippi and Missouri Rivers, 2004." United States Geological Survey. http://pubs.usgs.gov/sir/2006/5169/pdf/text.pdf >.
SDTF (1997) "A summary of ground application studies." Spray Drift Task Force. http://www.agdrift.com/PDF_FILES/Ground.pdf >.
Sellers, BA; Ferrell, JA; and MacDonald, GE (2011) "Herbicide Resistant Weeds." http://edis.ifas.ufl.edu/ag239 >.
Senseman, SA (2007) *Herbicide Handbook, Ninth Edition*. Weed Science Society of America.
Sharpe, T (2010) "Cropland Management (*Chapter 4*)." *Tarheel Wildlife: A Guide for Managing Wildlife on Private Lands in North Carolina*. Raleigh: North Carolina Wildlife Resources Commission. p 26-29. Last Accessed: November 9, 2010 < http://www.ncwildlife.org/tarheelwildlife/documents/Tarheel_Wildlife_ch_4.pdf >.
Shaw, DR; Culpepper, S; Owen, M; Price, A; and Wilson, R (2012) "Herbicide-resistant Weeds Threaten Soil Conservation Gains: Finding a Balance for Soil and Farm Sustainability." Council for Agricultural Science and Technology (CAST).

Smith, KA and Conen, F (2004) "Impacts of land management on fluxes of trace greenhouse gases." *Soil Use and Management.* 20 (2): p 255-63. http://dx.doi.org/10.1111/j.1475-2743.2004.tb00366.x >.

Smith, R and Smith, T (2003) *Elements of Ecology*. San Francisco Benjamin Cummings.

Southwood, T and Way, M (1970) "Ecological Background to Pest Management." *Concepts of Pest Management*. Raleigh, NC: North Carolina State University. p 7-28.

Soy Connection (2011) "Soyfoods Guide 2011." United Soybean Board. http://www.soyconnection.com/soyfoods/pdf/soyfoods_guide.pdf >.

Soy Stats (2011) "U.S. Soybean and Soy Products Exports 2010." American Soybean Board. http://www.soystats.com/2011/Default-frames.htm >.

Soy Stats (2012a) "U.S. Soybean Meal Production 1984 - 2011." http://www.soystats.com/2012/Default-frames.htm >.

Soy Stats (2012b) "World Soybean Production 2012." American Soybean Association. http://www.soystats.com/2012/Default-frames.htm >.

Steckel, LE and Montgomery, RR (2008) "Glyphosate Resistant Horseweed Control in Dicamba Glyphosate Resistant Soybeans."

Steenwerth, KL; Jackson, LE; Calderón, FJ; Stromberg, MR; and Scow, KM (2002) "Soil microbial community composition and land use history in cultivated and grassland ecosystems of coastal California." *Soil Biology and Biochemistry.* 34 (11): p 1599-611. http://www.sciencedirect.com/science/article/pii/S003807170200144X >.

Stewart, N; Halfhill, M; and Warwick, S (2003) "Transgene introgression from genetically modified crops to their wild relatives." *Nature Review Genetics.* 4 (10): p 806-17. http://dx.doi.org/10.1038/nrg1179-c2 >.

Stewart, SD; Layton, B; and Catchot, A (2007) "Common Beneficial Arthropods Found in Field Crops." http://www.extension.org/mediawiki/files/0/00/W127-Beneficials.pdf >.

Sundstrom, F; Williams, J; Van Deynze, A; and Bradford, K (2002) "Identity Preservation of Agricultural Commodities." Agricultural Biotechnology in California Series, Publication 8077. http://anrcatalog.ucdavis.edu/pdf/8077.pdf >.

Syngenta (2010) "Waterhemp Population in Central Illinois Seed Corn Production Field Resistant to HPPD-Inhibitor Herbicides." Syngenta USA. http://www.syngentacropprotection.com/news_releases/news.aspx?id=127116 >.

Syngenta (2011) "Callisto Label." Syngenta.

Taylor-Lovell, S; Sims, GK; and Wax, LM (2002) "Effects of Moisture, Temperature, and Biological Activity on the Degradation of Isoxaflutole in Soil." *Journal of Agricultural and Food Chemistry.* 50 (20): p 5626-33. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf011486l >.

The Keystone Center (2009) "Environmental Resource Indicators for Measuring Outcomes of On-Farm Agriculture Production in the United States." The Keystone Center.

The Organic & Non-GMO Report (2007) "USDA Organic Report: Soybean Acreage Down, Corn Acreage Up." The Organic & Non-GMO Report. http://www.non-gmoreport.com/articles/feb07/organic_corn_soybeans.php >.

Towery, D and Werblow, S (2010) "Facilitating Conservation Farming Practices and Enhancing Environmental Sustainability with Agricultural Biotechnology." http://www.ctic.purdue.edu/media/pdf/Biotech_Executive_Summary.pdf >.

UCA (2013) "Legumes." University of California. Last Accessed: January, 2013 < http://faculty.uca.edu/johnc/legumes3390.htm >.

University of Tennessee Agricultural Extension Service (2011) "Beaver Creek Study Final Report: Making a Splash AE03-63." http://economics.ag.utk.edu/bcstudy.html >.

US-NARA (2010) "Executive Orders disposition tables index." United States National Archives and Records Administration. http://www.archives.gov/federal-register/executive-orders/disposition.html >.

USB (2011a) "SoyStats 2011." United Soybean Board. http://www.soystats.com/2011/Default-frames.htm >.

USB (2011b) "US Soybean Production." United Soybean Board.

USDA-AMS (2010) "National Organic Program." United States Department of Agriculture - Agricultural Marketing Service. http://www.ams.usda.gov/AMSv1.0/nop >.

USDA-AMS (2013) "Pesticide Data Program Annual Summary, Calendar Year 2011." U.S. Department of Agriculture, Agricultural Marketing Service. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5102692 >.

USDA-APHIS (1997) "Environmental Assessment and Finding of No Significant Impact for Corn Line GA21." http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-APHIS (2011) "Assessment of Plant Pest Risk for MON 87701 Soybean." http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-APHIS (2012a) "Final Environmental Impact Statement - Glyphosate-Tolerant H7-1 Sugar Beet: Request for Nonregulated Status." Last Accessed: January, 2013 < http://www.aphis.usda.gov/brs/aphisdocs/03_32301p_feis.pdf >.

USDA-APHIS (2012b) "Petitions for Nonregulated Status Granted or Pending by APHIS " United States Department of Agriculture - Animal and Plant Health Inspection Service. http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-APHIS (2012c) "Petitions for Nonregulated Status Granted or Pending by APHIS " United States Department of Agriculture - Animal and Plant Health Inspection Service. Last Accessed: December, 2012 < http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-APHIS (2012d) "Plant Pest Risk Assessment of FG72 Soybean." http://www.aphis.usda.gov/biotechnology/not_reg.html >.

USDA-ERS (2007) "Emerging Issues in the U.S. Organic Industry - U.S. Market Growth Outpaces Domestic Supply." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/publications/eib55/eib55b.pdf >.

USDA-ERS (2010a) ""No-Till" Farming is a Growing Practice." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Publications/EIB70/EIB70.pdf >.

USDA-ERS (2010b) "Organic Production." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Data/Organic/ >.

USDA-ERS (2010c) "Soybean and Oil Crops: Background." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Briefing/SoybeansOilcrops/background.htm >.

USDA-ERS (2010d) "USDA Agricultural Projections to 2019." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Publications/OCE101/OCE101.pdf >.

USDA-ERS (2011a) "Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm >.

USDA-ERS (2011b) "Agricultural Chemicals and Production Technology: Soil Management." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/briefing/agchemicals/soilmangement.htm >.

USDA-ERS (2011c) "Agricultural Projections to 2020." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Publications/OCE111/OCE111.pdf >.

USDA-ERS (2011d) "The Changing Organization of US Farming." United States Department of Agriculture - Economic Research Service.

USDA-ERS (2011e) "The Ethanol Decade: An Expansion of U.S. Corn Production, 2000-09." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Publications/EIB79/EIB79.pdf >.

USDA-ERS (2011f) "Nitrogen Used on Soybeans, Rates per Fertilized Acre Receiving Nitrogen, Selected States 1964 - 2006." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Data/FertilizerUse/ >.

USDA-ERS (2011g) "Percentage of Soybean Acreage Receiving Nitrogen Fertilizer, Selected States 1964 - 2006." United States Department of Agriculture - Economic Research Service. http://www.ers.usda.gov/Data/FertilizerUse/ >.

USDA-ERS (2012a) "Adoption of Genetically Engineered Crops in the U.S. Genetically Engineered Soybean Varieties." United States Department of Agriculture - Economic Research Service. Last Accessed: December, 2012 < http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx >.

USDA-ERS (2012b) "Oil Crops Outlook." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/media/965281/ocs12l.pdf >.

USDA-ERS (2012c) "Soybean Commodity Costs and Returns." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/data-products/commodity-costs-and-returns.aspx >.

USDA-ERS "ARMS Farm Financial and Crop Production Practices." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/data-products/arms-farm-financial-and-crop-production-practices/tailored-reports.aspx >.

USDA-ERS "ARMS Survey: Crop Residue Management Practices for Soybean, 2006." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/data-products/arms-farm-financial-and-crop-production-practices/tailored-reports.aspx >.

USDA-ERS "Soybean Irrigation and Water Use." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/data-products/arms-farm-financial-and-crop-production-practices/tailored-reports.aspx >.

USDA-ERS (2013d) "USDA Agricultural Projections to 2022." United States Department of Agriculture - Economic Research Service. Last Accessed: January, 2013 < http://www.ers.usda.gov/media/1013582/oce131d.pdf >.

USDA-FAS "Global Agricultural Trade System." USDA-FAS. http://www.fas.usda.gov/gats/default.aspx >.

USDA-NASS. "Agricultural Chemical Usage - 1995 Field Crops Summary." United States Deparment of Agriculture - National Agricultural Statistics Service, 1996.

USDA-NASS (2002a) "Agricultural Chemical Usage - 2001 Field Crops Summary." United States Department of Agriculture - National Agricultural Statistics Service.

USDA-NASS. "Agricultural Chemical Usage - 2001 Field Crops Summary." United States Department of Agriculture - National Agricultural Statistics Service, 2002b.

USDA-NASS (2007a) "Agricultural Chemical Usage - 2006 Field Crops Summary." United States Department of Agriculture - National Agricultural Statistics Service.

USDA-NASS. "Agricultural Chemical Usage - 2006 Field Crops Summary." United States Department of Agriculture - National Agricultural Statistics Service, 2007b.

USDA-NASS "2010 Corn, Upland Cotton, and Fall Potatoes " United States Department of Agriculture - National Agricultural Statistics Service. http://www.nass.usda.gov/Data_and_Statistics/Pre-Defined_Queries/2010_Corn_Upland_Cotton_Fall_Potatoes/index.asp >.

USDA-NASS (2011b) "Acreage." United States Department of Agriculture - National Agricultural Statistics Service. http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2011.pdf >.

USDA-NASS "Quick Stats 2.0." United States Department of Agriculture. http://www.nass.usda.gov/Data_and_Statistics/Quick_Stats/index.asp >.

USDA-NASS (2012a) "2011 Certified Organic Production Survey." United States Department of Agriculture - National Agricultural Statistics Service. Last Accessed: October 2012 < http://usda01.library.cornell.edu/usda/current/OrganicProduction/OrganicProduction-10-04-2012.pdf >.

USDA-NASS "Soybean Acreage, 2002 - 2012." United States Department of Agriculture - National Agricultural Statistics Service. http://quickstats.nass.usda.gov/ >.

USDA-NASS "Soybean Acreage, U.S. States - 2012." United States Department of Agriculture - National Agricultural Statistics Service. http://quickstats.nass.usda.gov/ >.

USDA-NASS (2012d) "Soybeans 2011 Planted Acres by County for Selected States (map)." United States Dept. of Agriculture, National Agricultural Statistics Service. http://www.nass.usda.gov/Charts_and_Maps/Crops_County/pdf/SB-PL11-RGBChor.pdf >.

USDA-NASS (2013a) "2012 Agricultural Chemical Use Survey: Soybeans." USDA-NASS. http://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Chemical_Use/ChemUseHighlights-Soybeans-2012.pdf >.

USDA-NASS " 2012 Soybeans and Wheat Chemical Use." USDA-NASS. Last Accessed: June 7, 2013 < http://www.nass.usda.gov/Data_and_Statistics/Pre-Defined_Queries/2012_Soybeans_and_Wheat/index.asp >.

USDA-NASS "Barley, Corn, Cotton, Dry Beans, Dry Peas, Flaxseed, Millet, Oats, Rice, Sorghum, Soybean, Sugar Beet, and Wheat Acreage in Select U.S. states, 2012." United States Department of Agriculture - National Agricultural Statistics Service. Last Accessed: January, 2013 < http://quickstats.nass.usda.gov/ >.

USDA-NASS (2013d) "Farms, Land in Farms, and Livestock Operations 2012 Summary." U.S. Department of Agriculture–National Agriculture Statistics Service. http://usda01.library.cornell.edu/usda/nass/FarmLandIn//2010s/2013/FarmLandIn-02-19-2013.pdf >.

USDA-NASS "Quick Stats." United States Department of Agriculture - National Agricultural Statistics Service. Last Accessed: January, 2013 < http://quickstats.nass.usda.gov/ >.

USDA-NASS "US Soybean and Corn Production, 2002 - 2012." United States Department of Agriculture - Nationa Agricultural Statistics Service. Last Accessed: January, 2013 < http://quickstats.nass.usda.gov/#9788D2E0-00DD-33D5-808E-7D2BB1E8E510 >.

USDA-NASS "US Soybean Production by individual US states, 2002 - 2012." United States Department of Agriculture - Nationa Agricultural Statistics Service. Last Accessed: January, 2013 < http://quickstats.nass.usda.gov/#9788D2E0-00DD-33D5-808E-7D2BB1E8E510 >.

USDA-NASS "USDA Quick Stats 2.0 - Soybean Production and Value." United States Department of Agriculture - National Agricultural Statistics Service. Last Accessed: January, 2013 < http://quickstats.nass.usda.gov/ >.

USDA-NRCS (1999) "Conservation Tillage Systems and Wildlife." U.S. Department of Agriculture–Natural Resources Conservation Service. http://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs143_022212.pdf >.

USDA-NRCS (2001) "Soil Quality - Introduction." U.S. Department of Agriculture–Natural Resources Conservation Service. http://soils.usda.gov/sqi/publications/publications.html#agy >.

USDA-NRCS (2004) "Soil Biology and Land Management." U.S. Department of Agriculture–Natural Resources Conservation Service. http://soils.usda.gov/sqi/publications/publications.html#atn >.

USDA-NRCS (2006) "Conservation Resource Brief: Air Quality, Number 0605." National Resources Conservation Service. http://www.nrcs.usda.gov/feature/outlook/Air%20Quality.pdf >.

USDA-NRCS (2010) "Keys to Soil Taxonomy." U.S. Department of Agriculture–Natural Resources Conservation Service. http://soils.usda.gov/technical/classification/tax_keys/ >.

USDA-NRCS (2011) "Welcome to Energy Estimator: Tillage." United States Deparment of Agriculture - Natural Resources Conservation Services. http://ecat.sc.egov.usda.gov/ >.

USDA-OCE (2012) "USDA Agricultural Projections to 2021." Office of the Chief Economist, World Agricultural Outlook Board, U.S. Department of Agriculture. Prepared by the Interagency Agricultural Projections Committee.

USFWS (2011a) "Draft Environmental Assessment - Use of Genetically Modified, Glyphosate-Tolerant Soybeans and Corn on National Wildlife Refuge Lands in the Mountain–Prairie Region (Region 6)." http://www.fws.gov/mountain-prairie/planning/resources/documents/resources_gmo_ea.pdf >.

USFWS (2011b) "Species Profile for Delmarva Peninsula Fox Squirrel (Sciurus niger cinereus)." United States Fish and Wildlife Service. http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=A00B#lifeHistory >.

USFWS "Environmental Conservation System Online." United States Fish and Wildlife Services. Last Accessed: June 25, 2013 < http://ecos.fws.gov/tess_public/pub/stateListingAndOccurrence.jsp >.
USGS (2009a) "Isoxaflutole Herbicide, 2002 Estimated Annual Agricultural Use." Last Accessed: April 22, 2013 < http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=02&map=m9119 >.
USGS (2009b) "What is Groundwater." U.S. Geological Survey. http://pubs.usgs.gov/of/1993/ofr93-643/ >.
USGS (2011) "Surface Water Use in the United States 2005." U.S. Geological Survey. http://ga.water.usgs.gov/edu/wusw.html >.
Vaughan, DA; Lu, B-R; and Tomooka, N (2008) "The evolving story of rice evolution." *Plant Science.* 174 (4): p 394-408. http://www.sciencedirect.com/science/article/pii/S0168945208000198 >.
Vencill, WK; Nichols, RL; Webster, TM; Soteres, JK; Mallory-Smith, C; Burgos, NR; Johnson, WG; and McClelland, MR (2012) "Herbicide Resistance: Toward an Understanding of Resistance Development and the Impact of Herbicide-Resistant Crops." *Weed Science.* 60 (sp1): p 2-30.
Weeks, M to: Stankiewicz-Gabel, Rebecca (2013). BCS projections for IFT adoption in FG72 soybean.
Weirich, JW; Shaw, DR; Owen, MD; Dixon, PM; Weller, SC; Young, BG; Wilson, RG; and Jordan, DL (2011) "Benchmark study on glyphosate-resistant cropping systems in the United States. Part 5: Effects of glyphosate-based weed management programs on farm-level profitability." *Pest Management Science.* 67 (7): p 781-4. http://www.ncbi.nlm.nih.gov/pubmed/21538796 >.
Weller, S; Owen, M; and Johnson, W (2010) "Managing Glyphosate-resistant Weeds and Populations Shifts in Midwestern U.S. Cropping Systems." *Glyphosate Resistance in Crops and Weeds*. Hoboken, NJ: John Wiley & Sons, Inc. p 213-33.
West, TO and Marland, G (2002) "A synthesis of carbon sequestration, carbon emissions, and net carbon flux in agriculture: comparing tillage practices in the United States." *Agriculture, Ecosystems & Environment.* 91 (1-3): p 217-32. http://www.sciencedirect.com/science/article/pii/S016788090100233X >.
Wilson, E (1988) "Biodiversity." http://books.google.com/books/about/Biodiversity.html?id=bI3cc2IMq9MC >.
Wong, V; Levi, K; Baddal, B; Turton, J; and Boswell, TC (2011) "Spread of Pseudomonas fluorescens Due to Contaminated Drinking Water in a Bone Marrow Transplant Unit▿." *Journal of Clinical Microbiology.* 49 (6): p 2093-96.
WSSA (2012) " Introduction to the Special Issue ofWeed Scienceon Herbicide Resistance Management. ." *Weed Science.* 60 (Special Issue 1). http://www.wssajournals.org.pinnacle.allenpress.com/toc/wees/60/sp1 >.
Yoshimura, Y; Matsuo, K; and Yasuda, K (2006) "Gene flow from GM glyphosate-tolerant to conventional soybeans under field conditions in Japan." *Environmental Biosafety Research.* 5 (3): p 169-73.
Young, IM and Ritz, K (2000) "Tillage, habitat space and function of soil microbes." *Soil & Tillage Research.* 53 p 201-12.

Zapiola, ML; Campbell, CK; Butler, MD; and Mallory-Smith, CA (2008) "Escape and establishment of transgenic glyphosate-resistant creeping bentgrass Agrostis stolonifera in Oregon, USA: a 4-year study." *Journal of Applied Ecology*. 45 (2): p 486-94. http://dx.doi.org/10.1111/j.1365-2664.2007.01430.x >.

Zenk, P (2012) "Motivation Mounts for LibertyLink Soybeans
Expanding weed resistance plus new LL varieties could entice more Midwest growers." Corn & Soybean Digest. Last Accessed: April 18, 2013 < http://cornandsoybeandigest.com/seed/motivation-mounts-libertylink-soybeans >.

Zollinger, R (2013) "North Dakota Weed Control Guide." NDSU Extension Service. http://www.ag.ndsu.edu/weeds/weed-control-guides/nd-weed-control-guide-1 >.

9 APPENDIX A

RESTRICTED USE PESTICIDE

May injure (phytotoxic) susceptible non-target plants.

For retail sale to and use by certified applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification. Commercial and certified applicators must ensure that all persons involved in these activities are informed of the precautionary statements.

Bayer CropScience

EXP32032A SC Herbicide

For weed control in Isoxaflutole Tolerant Soybean varieties in the states of: Arkansas, Alabama, Colorado, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Mexico, North Dakota Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas and Wyoming. The states of Colorado, New Mexico, Missouri and South Dakota have established more restrictive conditions on the use of this product. Check with your state regulatory authority prior to use.

ACTIVE INGREDIENT:

Isoxaflutole* [5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole] 40.5%

INERT INGREDIENTS: 59.5%

*Product contains 4.0 pounds of isoxaflutole per gallon.

EPA Reg. No. 264-600 **E.P.A. Est. No. 11773-IA-1**

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: No specific antidote is available. All treatments should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.

1

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray mist.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some of the materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material such as polyethylene or polyvinyl chloride, shoes plus socks and protective eye wear. When mixing/loading or cleaning equipment, wear a chemical resistant apron in addition to the other required PPE. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROL STATEMENT

When handlers use closed systems, enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Drift or runoff may adversely affect non-target plants. Drift and runoff may be hazardous to aquatic organism in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

Do not apply when weather conditions favor drift from treated areas. Do not use the same spray equipment for other purposes unless thoroughly cleaned. Do not contaminate water used for irrigation or domestic purposes.

This chemical is known to leach through soil into shallow ground water under certain conditions as a result of agricultural use. Thus, use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

Isoxaflutole residues can contaminate surface water through spray drift. Under some conditions, isoxaflutole residues may also have a high potential for runoff into surface water (primarily via dissolution in runoff water), for several weeks after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, areas over-laying extremely shallow ground water, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips and areas over-laying tile drainage systems that drain to surface water.

In fields having sands, loamy sands and sandy loam soils, special care should be taken not to over-irrigate since substantial over-irrigation promotes the leaching of chemicals.

This pesticide is toxic to some plants at very low concentrations. Non-target plants may be adversely affected if the pesticide is allowed to drift from areas of application. Exposure to isoxaflutole residues may injure or kill susceptible plants. Symptoms of phytotoxicity as a result of exposure to isoxaflutole include whitening or chlorosis of the foliage of affected plants. Cotton is particularly susceptible to isoxaflutole; therefore, exposure of cotton to isoxaflutole residues may affect cotton yield. To prevent damage to crops and other desirable plants, read and follow all directions and precautions on this label before using.

This product may not be mixed or loaded within 50 feet of any wells (including abandoned wells and drainage wells), sink holes, perennial or intermittent streams and rivers, and natural or impounded lakes and reservoirs. This setback does not apply to properly capped or plugged abandoned wells and does not apply to impervious pad or properly diked mixing/loading areas.

Operations that involve mixing, loading, rinsing or washing of this product into or from pesticide handling or application equipment or containers within 50 feet of any well are prohibited unless conducted on an impervious pad constructed to withstand the weight of the heaviest load that may be positioned on or moved across the pad. Such a pad shall be designed and maintained to contain any product spills or equipment leaks, container or equipment rinse or washwater and rainwater that may fall on the pad. Surface water shall not be allowed to either flow over or from the pad, which means the pad must be self-contained. The pad shall be sloped to facilitate material removal. An unroofed pad shall be of sufficient capacity to contain at a minimum 110% of the capacity of the largest pesticide container or application equipment on the pad. A pad that is covered by a roof of sufficient size to exclude completely precipitation from contact shall be of sufficient capacity to contain at a minimum of 100% of the capacity of the largest pesticide container or application equipment on the pad. Containment capacities as described above shall be maintained at all times. The above specific minimum containment capacities do not apply to vehicles when delivering pesticide shipments to the mixing/loading site. States may have in effect additional requirements regarding wellhead setbacks and operational containment.

Product must be used in a manner which will prevent back siphoning in wells, spills or improper disposal of excess pesticide, spray mixtures or rinsates.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the same area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticides.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil or water, is coveralls over long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, socks plus chemical resistant footwear and protective eye wear.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or (or equivalent) promptly after emptying Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

INFORMATION

EXP32032A SC Herbicide is formulated as a soluble concentrate of isoxaflutole at a concentration of 4 pounds of active ingredient, isoxaflutole, per gallon. EXP32032A SC Herbicide is a selective herbicide for control of important broadleaf and grass weeds infesting soybean (for use only in IFT Tolerant Soybean varieties) when used as a preplant (surface-applied or incorporated), preemergence, or early postemergence herbicide.

Do not irrigate EXP32032A SC Herbicide into coarse soils at planting time when soils are saturated.

Do not apply this product through any type of irrigation system.

Do not apply this product using aerial application equipment.

Do not use flood or furrow irrigation to apply, activate or incorporate this product.

MIXING INSTRUCTIONS

Application with water: Fill the spray tank 1/4 to 1/2 of the required volume of water prior to the addition of EXP32032A SC Herbicide. Add the proper amount of EXP32032A SC Herbicide, then add the rest of the water to the desired level. Maintain sufficient agitation to ensure a uniform spray mixture during application. If EXP32032A SC Herbicide is applied in a tank mixture with other pesticides, add EXP32032A SC Herbicide to the spray tank first and ensure it is thoroughly dispersed before adding other pesticides. Continue to fill the tank with carrier to the desired volume while agitating. **CONTINUE AGITATION DURING APPLICATION TO ENSURE A UNIFORM SPRAY MIXTURE.**

Re-suspending SC Products in Spray Solution: Like other suspension concentrates (SC's), EXP32032A SC Herbicide will settle if left standing without agitation. If the spray solution is allowed to settle for one hour or more, reagitate the spray solution for a minimum of 10 minutes before application.

Sprayer Cleanup: To avoid injury or exposure to non-target crops, thoroughly clean all mixing and spray equipment, including pumps, nozzles, lines and screens with a good quality tank cleaner, on approved rinse pad or on the field site where an approved crop is to be grown.

TANK MIXTURES

EXP32032A SC Herbicide can be applied in tank mixture with many other pesticides registered for use on approved crops. Refer to "Tank Mix Combination" section for recommendations and other restrictions.

COMPATIBILITY

If EXP32032A SC Herbicide is to be tank mixed or other pesticides, compatibility should be tested prior to mixing. To test for compatibility, use a small container and mix a small amount (0.5 to 1 qt) of spray, combining all ingredients in the same ratio as the anticipated use. If any indications of physical incompatibility develop, do not use this mixture for spraying. Indications of incompatibility usually will appear within 5-15 minutes after mixing. Read and follow the label of each tankmix product used for precautionary statements, directions for use, geographic and other restrictions.

APPLICATION PROCEDURES

APPLICATION TIMING

EXP32032A SC Herbicide may be applied only in Isoxaflutole (IFT) Tolerant Soybean varieties either preplant, preplant incorporated (less than 2" deep), preemergence, or early postemergence (up to but not including first bloom).

EXP32032A SC Herbicide treatments are most effective in controlling weeds when adequate rainfall is received within 14 days after application. If cultivation is necessary because of soil crusting, soil compaction or weed germination before rain occurs, use shallow tillage such as rotary hoe to lightly incorporate EXP32032A SC Herbicide. If treated soil is moved during tillage practices in such a way that the herbicide barrier is no longer intact, weeds may emerge from areas where treated soil has been removed. Do not incorporate with a drag harrow after planting.

Preplant Surface-Applied: EXP32032A SC Herbicide may be applied up to 21 days before planting IFT Tolerant Soybean; Refer to the label of the respective sequential partner for specific use directions. Total EXP32032A SC Herbicide applied should equal the rate recommended (See Rate Tables) for a preplant treatment on the predominate soil type in the field. Moving treated soil out of the row or moving untreated soil to the surface during planting may result in reduced weed control.

Preplant Incorporated: EXP32032A SC Herbicide may be applied up to 21 days before planting soybean; Refer to the label of any respective sequential partner for specific use directions. Apply to the soil and uniformly incorporate in the top two inches of soil before planting using a finishing disc harrow, field cultivator or similar implement capable of providing uniform two inch incorporation. Do not incorporate EXP32032A SC Herbicide deeper than 2" or weed control may be reduced.

Preemergence: Apply EXP32032A SC Herbicide during planting (behind the planter after furrow closure) or after planting, but before weeds or crop emerge.

Early Postemergence: Apply EXP32032A SC Herbicide to soybean (IFT Tolerant Soybean varieties) at growth stages up to but not including first bloom.

GROUND APPLICATION

AVOID SPRAY OVERLAPS AS EXCESSIVE RATES MAY RESULT IN ADVERSE CROP RESPONSE.

Apply EXP32032A SC Herbicide in a minimum of 10 gallons of spray mixture per acre. Uniform, thorough spray coverage is important to achieve consistent weed control. To minimize spray drift to non-target areas, apply this product using nozzles which deliver a coarse or larger spray droplet as defined by ASAE standard S-572 and as shown in nozzle manufacturer's catalogues. Keep the spray boom at the lowest possible spray height above the target surface.

Refer to nozzle manufacturer's recommendations for proper nozzle, pressure setting and sprayer speed for optimum product performance and minimal spray drift. Use sprayers that provide accurate and uniform application.

Uneven application, sprayers not properly calibrated, or improper incorporation may decrease the level of weed control and/or increase the level of adverse crop response. Over applications or boom overlapping may result in stand loss.

Maintain constant ground speed while applying product to ensure proper distribution. **MAINTAIN ADEQUATE AGITATION AT ALL TIMES, INCLUDING MOMENTARY STOPS.**

RESTRICTIONS FOR USE ON IFT TOLERANT SOYBEAN

Do not graze the treated crop or cut for hay.

Do not apply aerially.

In the States of AL, CO, GA, KS, KY, LA, MO, MS, SC and TN, if the water table (i.e, level of saturation) is less than 25 feet below the ground surface, do not use on soils meeting all three of the following criteria (if less than three criteria are met or the water table is greater than 25 feel below the ground surface, there is no restriction against application):

- **The surface soil texture is loamy sand or sand**
- **The subsoil texture is loamy sand or sand**
- **The average organic matter (in the upper 12 inches) is less than 2% by weight**

In the States of IA, IL, IN, MT, ND, NE, OH, PA, SD and WY, if the water table (i.e, level of saturation) is less than 25 feet below the ground surface, do not use on soils meeting all three of the following criteria (if less than three criteria are met or the water table is greater than 25 feel below the ground surface, there is no restriction against application):

- **The surface soil texture is sandy loam, loamy sand or sand**
- **The subsoil texture is loamy sand or sand**
- **The average organic matter (in the upper 12 inches) is less than 2% by weight**

Do not apply more than 3.0 fluid ounces of EXP32032A SC Herbicide per acre in one season (365 day period) or exceed the maximum label rate for any given soil type. **Do not** make more than one application of this product in one season (365 day period)

Application of EXP32032A SC Herbicide at less than recommended rates for the appropriate soil will only provide suppression of sensitive weeds.

PRECAUTIONS FOR USE ON SOYBEAN (IFT Tolerant Soybean varieties only)

EXP32032A SC Herbicide applications to **coarse soils** with organic matter of less than 1.5% by weight **or** pH greater than 7.5 may cause adverse crop response.

The use of EXP32032A SC Herbicide is not recommended on soils that have organic matter of less than 1.5% **and** a pH greater than 7.5.

Use on clay knolls, eroded hill sides, terracing with scraped exposed subsoil, or other areas of coarser and/or lower organic matter soils, may cause adverse crop response.

To prevent off-site movement of soil containing this product to non-target areas, do not apply EXP32032A SC Herbicide to areas receiving less than 15 inches of average annual precipitation unless supplemented to at least the equivalent of 15 inches of annual precipitation with irrigation water.

ROTATIONAL CROP RESTRICTIONS

Rotational crops vary in their crop response to low concentrations of EXP32032A SC Herbicide remaining in the soil. The amount of EXP32032A SC Herbicide that may be present in the soil depends on soil moisture, soil temp, application rate, elapsed time since application and other environmental factors. When EXP32032A SC Herbicide is used in combination with other products, always follow the most restrictive rotational crop requirements.

The following rotational crops may be planted after applying EXP32032A SC Herbicide in Soybean (IFT Tolerant Soybean varieties only):

Rotational Interval	Crop	Geography	Precipitation Requirement[1]
0 Months	Corn (Field), IFT tolerant soybean	All	None
4 Months	Wheat	All	None
6 Months	Soybeans (not tolerant to IFT), Barley, Sweetcorn, Popcorn, Potato, Grain, Oats, Rye, Sorghum, and Sunflower	All	None
10 Months	Cotton, Peanuts, Rice	All	None
	Alfalfa	All	15 inches of cumulative precipitation from application to planting of rotational crop.*
10 Months	Sugarbeets	East of the Mississippi River	15 inches of cumulative precipitation from application to planting of rotational crop.*
12 Months	Carrots	All	15 inches of cumulative precipitation from application to planting of rotational crop.*
18 Months	Sugarbeets	West of the Mississippi River	15 inches of cumulative precipitation from application to planting of rotational crop.*
18 Months	All other crops	All	15 inches of cumulative precipitation from application to planting of rotational crop.*
			*Furrow or Flood irrigation not to be included in total. No more than 7 inches of overhead irrigation included in total.

[1]The amount of cumulative precipitation required before planting a rotational crop is in addition to the required rotational interval given in months. Furrow or Flood irrigation is not to be included in total and no more than 7 inches of overhead irrigation is to be included in the cumulative precipitation required before planting a rotational crop.

Specific Use Directions

EXP32032A SC HERBICIDE APPLIED ALONE, AS A TANK-MIX OR AS PART OF A PLANNED SEQUENTIAL PROGRAM FOR WEED CONTROL IN ISOXAFLUTOLE (IFT) TOLERANT SOYBEAN VARIETIES

Application Timing[1]	Fluid Ounces of EXP32032A SC Herbicide per Acre per 365 Days				
	Soil Texture				
	Coarse Soils Sand, Loamy sand, Sandy loam		Medium Soils Loam, Silt loam, Silt, Sandy clay loam		Fine Soils Silty clay loam, Clay loam, Sandy clay, Silty clay, Clay
	1.5% O.M.[2] or less	> 1.5% O.M.	1.5% O.M. or less	>1.5% O.M.	
Preplant (Surface Applied or Incorporated): Early - 8 to 30 days prior to planting	Not Recommended (See Below)[3]	2.5	3.0		
Preplant (Surface Applied or Incorporated): 0 to 7 days prior to planting. Preemergence Early postemergence	Not Recommended (See Below)[3]	2.0	2.5	3.0	

EXP32032A SC Herbicide may be applied up to 30 days prior to planting when used in a planned sequential application program such as EXP32032A SC Herbicide followed by glyphosate or other post applied herbicides when plants are also tolerant to such herbicides.

[2]O.M. = Organic Matter by weight

EXP32032A SC Herbicide applications to **coarse soils** with organic matter of less than 1.5% by weight or pH greater than 7.5 may cause adverse crop response. The use of EXP32032A SC Herbicide is not recommended on soils that have organic matter of less than 1.5% and a pH greater than 7.5. Use on clay knolls, eroded hill sides, terracing with scraped exposed subsoil, or other areas of coarser and/or lower organic matter soils, may cause adverse crop response. To prevent off-site movement of soil containing this product to non-target areas, do not apply EXP32032A SC Herbicide to areas receiving less than 15 inches of average annual precipitation unless supplemented to at least the equivalent of 15 inches of annual precipitation with irrigation water

TANK MIX COMBINATIONS

Tank mixtures with EXP32032A SC Herbicide are allowed unless otherwise specified by the respective product labels. Check all tank mix product labels for proper rates and compatibilities for multiple tank mixes. EXP32032A SC Herbicide provides residual control of important grass and broadleaf weeds. Tankmix partners may be added for the control of emerged weeds as follows:

Prior to emergence: glyphosate, Ignite.
Post emergence to the crop: glyphosate or Ignite, when plants are also tolerant to such herbicides.

When using EXP32032A SC Herbicide on fields with variable soils, optimum weed control will result when overall application rate is based on the predominant soil type(s) within a field. Use on clay knolls, eroded hill sides, terracing with scraped exposed subsoil, or other areas of coarse soils with organic matter of less than 1.5% by weight, rate should be reduced to one half the rate used on the predominant soil type in the field, not to exceed one fluid ounce per acre.

EVALUATION LIST OF BROADLEAF AND GRASS WEEDS CONTROLLED BY EXP32032A SC HERBICIDE in IFT TOLERANT SOYBEAN

Broadleaf Weeds (C = Weeds Controlled, PC = Partial Control)	EXP32032A SC Herbicide Alone		Grassy Weeds (C = Weeds Controlled, PC = Partial Control)	EXP32032A SC Herbicide Alone
Amaranth, Palmer	C		Barnyardgrass	C
Buffalobur	C		Crabgrass, large	C
Burcucumber	PC		Crabgrass, smooth	C
Buttercup, small flower	C		Cupgrass, woolly	C
Carpetweed			Foxtail, bristly	C
Chamomile spp.	C		Foxtail, giant	C
Chickweed, common	C		Foxtail, green	C
Cocklebur*			Foxtail, robust purple	C
Copperleaf, hophornbeam	C		Foxtail, robust white	C
Dandelion (seedling)	C		Foxtail, yellow	C
Deadnettle, purple	C		Goosegrass	C
Galinsoga	C		Johnsongrass, seedling	C
Henbit	PC		Panicum, fall	C
Jimsonweed	C		Panicum, Texas	C
Kochia	C		Proso millet, wild	C
Lambsquarters, common	C		Sandbur, field	PC
Mallow, Venice	C		Shattercane	PC
Marestail	C		Signalgrass, broadleaf	C
Morningglory, annual*			Witchgrass	
Wild mustard	C			
Nightshade, black	C			
Nightshade, eastern black	C			
Nightshade, hairy				
Pennycress, field	C			
Pepperweed, virginia	C			
Plantain, broadleaf	C			
Pigweed, prostrate	C			
Pigweed, redroot	C			
Pigweed, smooth	C			
Purslane, common	C			
Radish, wild	C			
Ragweed, common	C			
Ragweed, giant*	PC			
Russian Thistle	C			
Shepherds-purse	C			
Smartweed, Pennsylvania	C			
Spurge, toothed	C			
Sunflower, wild*				
Velvetleaf	C			
Waterhemp, common	C			
Waterhemp, tall	C			

C= Control PC=Partial control***

* These weeds may require a postemergence application of glyphosate or Ignite, when plants are also tolerant to such herbicides..

**Partially controlled weeds will be stunted in growth and/or be reduced in number as compared to non-treated areas; performance may not be commercially acceptable. The degree of weed control will vary with weed size, density, spray coverage, and/or growing conditions.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET CONTENTS: 45 fluid ounces

Ignite is a registered trademark of Bayer.

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

EXP32032A SC Herbicide /IFT TOLERANT SOYBEAN VARIETIES (PENDING) 06/15/2010

10 APPENDIX B

How Researchers Estimate the Area of Herbicide-Resistant Weed Infestations.

There are two points that need to be made about the area estimates for herbicide-resistant weeds.

1. There is a very wide margin of error in the area estimates for herbicide-resistant weeds.

2. Many of the estimates are out of date.

This article is aimed at making users aware of how researchers estimate the area of herbicide-resistant weeds and the limitations of the data.

Estimating the area of herbicide-resistant weeds is a difficult task fraught with hidden traps. The International Survey of Herbicide-Resistant Weeds asks weed scientists to estimate the number of sites and the area infested with each unique case of herbicide-resistant weeds in their state/region. The aim of these questions was to get a very general idea of the scale of resistance problems in order to identify which herbicide-resistant weeds were causing the greatest economic impact. It was known from the beginning that the area estimates would have a very wide margin of error, however it was felt that some best "guestimate" from qualified weed scientists would be better than nothing.

Figure 1 shows the range of values that researchers can select for the number of sites (fields) of herbicide-resistant weeds, and Figure 2 shows the values for the estimated area of infestation. These area estimates are one value for the whole of the region being estimated (country or state), encompassing all crops.

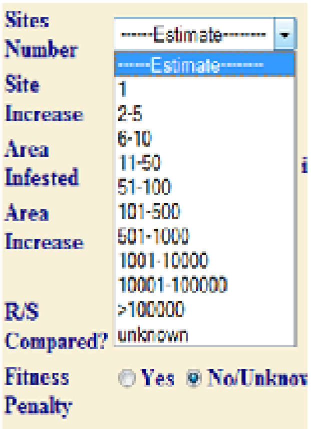


Figure 1. Values researchers can input for the estimate of the number of sites infested by herbicide-resistant weeds.

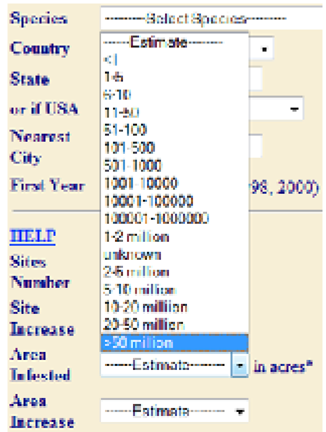


Figure 2. Values researchers can input for the estimate of area infested by herbicide-resistant weeds.

Table 2 presents the primary ways in which weed researchers estimate the area of infestation of herbicide-resistant weeds. For the great majority of estimates recorded in the database researchers rely upon a combination of field observations and passive testing, along with their own general knowledge of the biology and distribution of the weed species (Table 2). As indicated in Table 2 this often leads to an overestimation of the area infested with herbicide-resistant weeds. The most practical way to get an accurate estimate of herbicide-resistant weed infestations is to conduct "Random Field Sampling". Random field sampling is very expensive and time consuming and therefore is rarely done. There are many good examples of random field studies in the literature, in particular those conducted in the USA on glyphosate-resistant Horseweed (*Conyza canadensis*) (Kruger et al. 2009), in Canada on Accase inhibitor resistant Wild oat (*Avena fatua*) (Beckie et al. 2008), and in Australia on multiple resistance in Rigid Ryegrass (*Lolium rigidum*) (Llewellyn and Powles. 2001).

Table 1. Methods researchers have used to Estimate the Area of a Herbicide-Resistant Weed Infestation, from least accurate to most accurate.

METHOD	EXPLANATION
Field Observations	• Field observations may have some validity if done by an experienced weed scientist (not through second hand reports) if they know what factors to look for to suspect resistance. • Field observations are less reliable if the weed scientist relies upon second hand reports extension agents, farmers, ag chem dealers, and industry reporting "suspected cases". • Field observations that are not backed up by scientific tests are prone to error. Environmental conditions at herbicide application may lead to widespread weed control failure in a region on a particular species, resulting in many "suspected cases". For example there have been many reports of glyphosate-resistant common lambsquarters that have proven to be susceptible after lab and field testing.
Passive Testing	• The researcher receives samples suspected of resistance from growers, ag chem dealers, industry, and extension agents. • The samples are tested for resistance and researchers use the information gained to make assumptions about the prevalence of resistance in their state.

	• Some researchers make errors when using this test data to estimate the prevalence of resistance. For instance they may find 60% of the samples that they test are resistant, and then conclude 60% of the fields in their state (or the test region) are infested with resistant weeds. This is not the case as the collection of samples was biased, only samples highly suspected of resistance are submitted for testing. This leads to a massive overestimation of resistance.
Active Testing	• At weed seed maturity the weed scientist travels in the test area looking for heavy infestations of target species. • They collect samples from fields where resistance is highly suspected and then test for resistance. • Researchers then report the percentage of samples that test positive for resistance and often make the same mistake as above (passive testing) by concluding that this indicates the percentage of fields in a region that have resistance.
Elevator Samples	• If the weed seed and crop seed is of similar size and difficult to screen out then extracting weed seeds from grain samples (at grain delivery points) can be a cost effective method of estimating the area of herbicide-resistant weed infestations. • Researchers conduct random sampling of grain from the elevator - recording the origin of each sample and the percentage of grain samples that contain the target species. • Once samples are collected researchers test for resistance and report the percentage of grain samples (including those that did not have any weed seed contamination) with resistance. • Researchers can then multiply the acres of crop in the test region by the percentage of resistant samples to get a rough estimate of the area infested with herbicide-resistant weeds. • This method only works for select weed/crop combinations. For instance it works very well for wild oat samples in wheat (Beckie et al. 2008) but not for pigweed species in corn.
Random Field Sampling Most Practical Scientific Technique Beckie et al. 2008, Kruger et al. 2009, Llewellyn and Powles 2001	• Researchers first define the target weed species to be tested (ie: Waterhemp and Common Ragweed), the target crops (ie: corn, soybean) and the test area (counties, region). • Using GIS, they overlay a grid onto the test area with an appropriate amount of sample points (each intersection of the grid will be a sample location). • They can then determine the GPS locations of each of the grid intersections and at weed seed maturity they can travel to each grid intersection (using GPS) and sample from the nearest field with the target crop. • At each site they record the estimated densities of target species and record the percentage of fields that do not have the species present. • They then collect weed seed samples using appropriate sampling techniques within the field and follow a standard protocol for each sample site (eg: sampling in a W configuration over 1 acre from more than 40 plants). • Once samples are tested for resistance they can then calculate the percentage of fields infested with resistant weeds and multiply by the acres of crop in the test region to get the area infested.

Weed scientists have long had guidelines on how to screen for and document resistance (Heap, 1999, Beckie et al. 2000) however they have no guidelines on how to estimate the area of herbicide-resistant weed infestations, nor do they record how they have estimated the area of infestation at the time they enter their data into the survey. This leads to great uncertainty and error in the data because researchers are using different criteria to estimate herbicide-resistant weed infestations. To rectify this we aim to develop guidelines soon and to redesign the database to allow the collection of more detailed data on the distribution of herbicide-resistant weed infestations.

Estimates are out of date

Researchers are eager to report the first case of a new resistant weed biotype in their state, and typically they will update the case for the first two years after it is reported. But as their interests turn to different cases of herbicide-resistant weeds or other research they do not continue to update the case. These are effectively abandoned entries, and will remain that way until:

1. The researcher receives enough prompting to update the case
2. Another researcher becomes interested in the case and picks it up.

In the Quik Stats section of each case you will find the date that the case was last updated.

QUIK STATS (last updated Mar 05, 2009)

We aim to prompt researchers to update cases on a regular basis.

REFERENCES

Beckie, H. J., Heap, I. M., Smeda, R. J. and L. M. Hall. 2000. Screening for Herbicide Resistance in Weeds. Weed Technology, Vol. 14, No. 2 pp. 428-445

Beckie, H. J., Leeson, J. Y., Thomas, A. G., Hall, L. M., and C. A. Brenzil. 2008. Risk Assessment of Weed Resistance in the Canadian Prairies. Weed Technology, Vol. 22, No. 4 pp. 741-746

Heap, I. M. 1999. Criteria for confirmation of herbicide-resistance. The International Survey of Herbicide Resistant Weeds. Online. Available www.weedscience.com.

Llewellyn, R. S., and S. B. Powles. 2001. High Levels of Herbicide Resistance in Rigid Ryegrass (Lolium rigidum) in the Wheat Belt of Western Australia. Weed Technology, Vol. 15, No. 2 pp. 242-248

Kruger, G. R., Davis, V. M., Weller, S. C., Stachler, J. M., Loux, M. M. and W. G. Johnson. 2009. Frequency, Distribution, and Characterization of Horseweed (Conyza canadensis) Biotypes with Resistance to Glyphosate and ALS-Inhibiting Herbicides. Weed Science, Vol. 57, No. 6 pp. 652-659.

11 APPENDIX C: ISOXAFLUTOLE – DESCRIPTION AND CURRENT USES

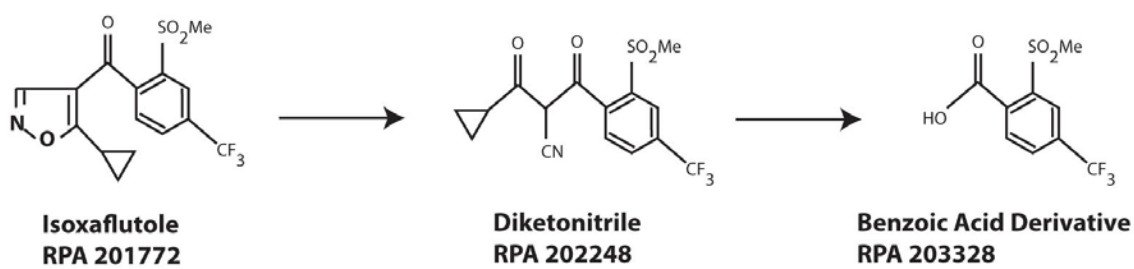
Description and Mode of Action

Isoxaflutole (isoxaflutole) is a systemic, broad-spectrum herbicide initially developed for the control of problematic broadleaf and grass weeds in corn (*Zea mays*) and sugarcane (RSC, 2011). Degradation of isoxaflutole yields two sequential metabolites and may be mediated through metabolic or physical/chemical pathways (Figure C1). Following foliar absorption or root uptake, a rapid and non-enzymatic process sequentially converts isoxaflutole into a diketonitrile derivative (Pallett et al., 1998). Diketonitrile is the major bioactive principle of isoxaflutole, and thus, primarily responsible for the herbicidal activity of isoxaflutole. Diketonitrile is further degraded into a benzoic acid derivative (Pallett et al., 1998). Degradation or metabolism of isoxaflutole into diketonitrile and the benzoic acid derivative is known to occur in soil, plants, and animals (EPA, 2011c).

isoxaflutole is classified as a Group F2 bleaching herbicide (isoxazole chemical family) under the Herbicide Resistance Action Committee (HRAC). This is a relatively novel group of herbicides and includes the triketone (e.g., mesotrione and sulcotrione) and pyrazole (e.g., benzofenap, pyrazolynate, and pyrazoxyfen) chemical families (HRAC, 2012). In contrast to other carotenoid-inhibiting herbicide groups (e.g., F1 and F3), isoxaflutole possesses a unique mode of action (MOA). isoxaflutole, through degradation to its bioactive principle, targets 4-hydroxy phenylpyruvate dioxygenase (4-HPPD). Competitive inhibition of 4-HPPD by diketonitrile reduces availability of cellular plastoquinone, an essential co-factor for phytoene desaturase activity in carotenoid biosynthesis (Figure C2). Consequently, a depletion of carotenoids impairs chloroplast development, leading to the typical bleaching of emerging foliar tissue and stunting of isoxaflutole -susceptible plant species (Pallett et al., 2001). Resistance to isoxaflutole may be conferred by more rapid degradation of diketonitrile benzoic acid derivative *in planta* (Pallett et al., 1998; RSC, 2011).

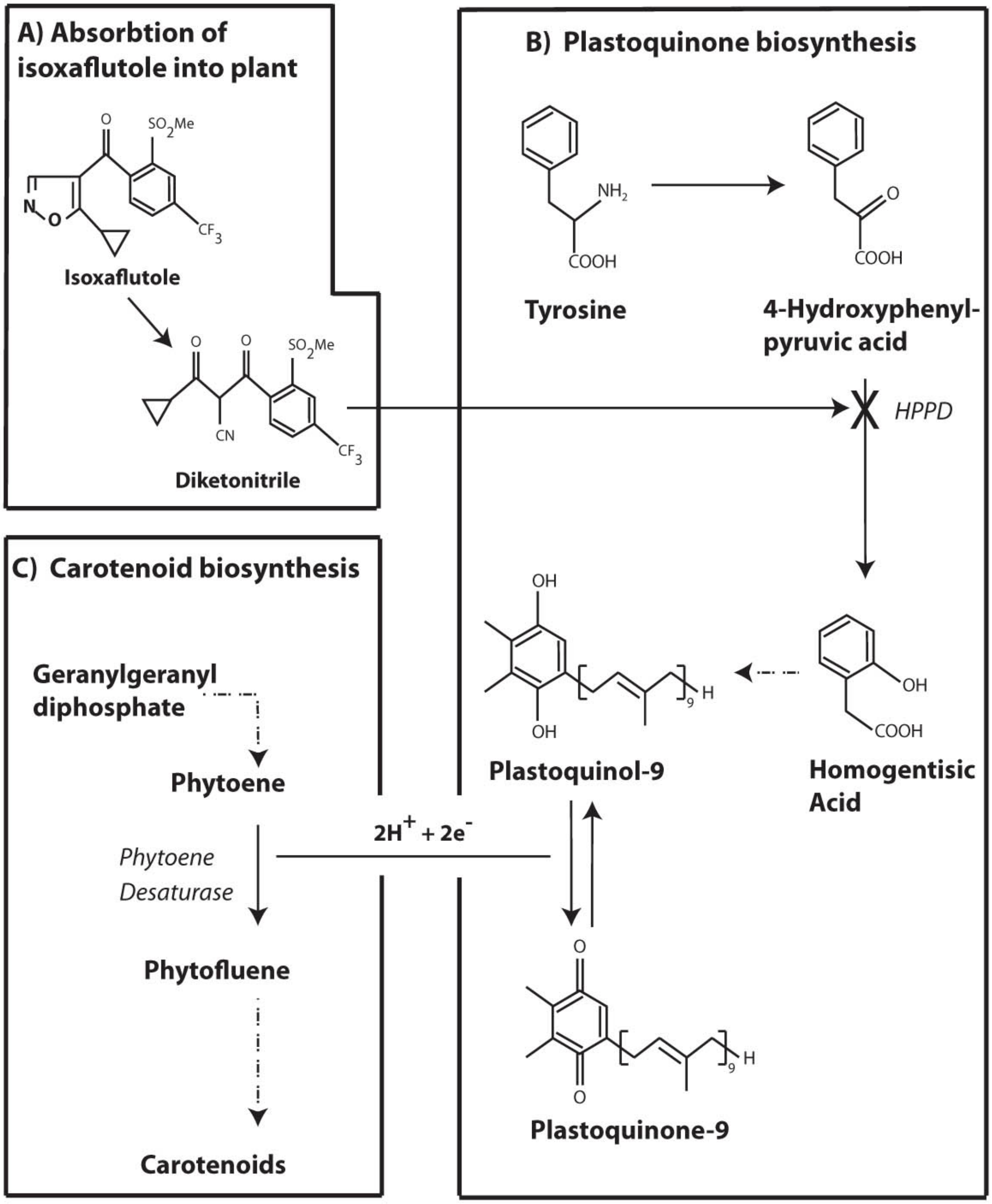
Herbicidal activity requires isoxaflutole or diketonitrile. Field soil half-life of isoxaflutole and diketonitrile are 0.4 – 4.5 and 10 – 39 days, respectively (Table C1). Aquatic photolysis half-life of isoxaflutole is 6.7 days; diketonitrile is relatively stable in laboratory aquatic conditions, though dissipation half-life from sediment/water systems is 66 – 89 days (Ramanarayanan et al., 2005). The benzoic acid derivative is not considered toxicologically significant, and thus, does not display herbicidal activity against plants (EPA, 2011c).

Figure C1. Metabolic/degradative fate of isoxaflutole in plants and soil



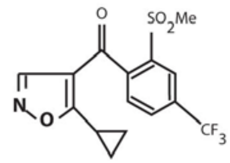
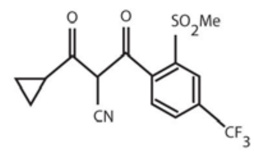
Reproduced from Pallett et al. (2001)

Figure C2. Activity of isoxaflutole in plants



(A) Degradation of isoxaflutole yields a diketonitrile derivative *in planta*. (B) The diketonitrile derivative reduces carotenoid biosynthesis through inhibition of the 4-HPPD enzyme, thus precluding the production of the plastoquinol-9 cofactor necessary for (C) phytoene desaturase activity. Adapted from Pallett et al. (1998).

Table C1. Summary of environmental fate information for isoxaflutole and diketonitrile

Property	IFT	DKN
mol structure		
mol wt (g/mol)	359	359
water solubility (mg/L)	6.2	325
octanol/water partition coefficient (log P)	2.32	-0.40
vapor pressure (pa)	1.0 x 10-6 (at 25C)	N/A
soil Koc at initial soil conc (~0.29 ppm)	102-227	62-204
lab aerobic soil half-life (days)	0.3-4.3	10-39
field dissapation half-life (days)	0.4-4.5	6.5-21
hydrolysis half-life at pH 7 (days)	0.84	stable
dissapation half-life from water phase in sediment/water systems (days)	0.5-0.6	66-89
aquatic photolysis half-life (natural sunlight at pH 7) (days)	6.7	stable

Reproduced from Ramanarayanan et al. (2005)

Regulatory Status of Isoxaflutole

The following is a summary of the Environmental Protection Agency (EPA) document entitled *Isoxaflutole Summary Document Registration Review: Initial Docket June 2011* (EPA, 2011a). Additional section-specific information may be found in that document.

All pesticides distributed or sold in the U.S. are subject to registration by the EPA under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Registration of a pesticide is dependent on consideration of scientific data demonstrating that a particular pesticide will not cause unreasonable risks to human health, workers, or the environment when used as directed on a product label. Isoxaflutole was first conditionally registered on September 15, 1998. The conditional registration was extended on April 11, 2002 and unconditionally registered on October 8, 2004 (Montague, 2012). Isoxaflutole is currently registered as a Restricted Use Pesticide due to non-target phytotoxicity concerns. In contrast to General Use Pesticides, isoxaflutole must be applied by or under the supervision of a certified applicator. At present, active EPA registrations include:

- 8 Section 3 Registrations.
- 20 Section 24(c) Special Local Need Registrations.
- 1 Section 5 Experimental Use Permit (for use on isoxaflutole - resistant soybean).

The Food Quality and Protection Act of 1996 mandated that the EPA conduct registration reviews of all pesticides distributed or sold in the U.S. every 15 years. Pursuant to Section 3(g) of FIFRA, EPA initiated a registration review for isoxaflutole in June 2011 (Docket Number:

EPA-HQ-OPP-2010-0979). EPA has developed an estimated timeline for the isoxaflutole registration review process. This is reproduced below in Table C2:

Table C2. Estimated isoxaflutole registration review timeline

Registration Review for Isoxaflutole - Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and Public Comment Period	2011 - June
Close Public Comment	2011 - August
Case Development	
Final Work Plant	2011 - November
Issue DCI	2012 - July - Sep.
Data Submission	2014 - July - Sept.
Open Public Comment Period for Draft Risk Assessment	2016 - Jan. - March
Close Public Comment Period	2016 - April - June
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	2016 - July - Sept.
Close Public Comment Period	2016 - Oct. - Dec.
Registration Review Decision and Begin Post-Decision Follow-up	2017
Total (years)	6

Conclusions from Previous Isoxaflutole Assessments

The following is a summary of the EPA document *Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole* (EPA, 2011c). Additional information specific to this section may be found in that document.

An ecological risk assessment was completed by the EPA Environmental Fate and Effects Division (EFED) on May 2, 1997 (DP barcodes 225503+) for the proposed registration of isoxaflutole as a pre-plant or pre-emergence herbicide for the control of grassy and broadleaf weeds in field corn. A brief summary of the risks from the proposed use of isoxaflutole is provided below:

- There is a phytotoxic risk to non-target aquatic and terrestrial plants from runoff of parent isoxaflutole and its degradation products.
- There is a phytotoxic risk to non-target terrestrial plants from found spray drift of parent isoxaflutole.
- Minimal adverse effects to non-target plants are expected from ground spray drift.

- Endangered plant species may be directly affected by the use of isoxaflutole.
- Chronic risks to birds, mammals, shrimp, and estuarine fish cannot be determined because data on the degradation products have not been received. [Note that data submitted subsequent to the 1997 assessment has indicated that only the Agency's level of concern (LOC) for chronic risk to estuarine invertebrates is exceeded at rates of application at corn sites. Chronic risks LOCs to birds, mammals, and fish are not exceeded.]
- EFED expects that degradation products will persist and accumulate in surface water and shallow ground water surrounding treated areas. [Note that updated data since the 1997 assessment supports this finding. Laboratory studies suggest that diketonitrile and the benzoic acid derivative are stable to hydrolysis and photolysis in aqueous systems and hence pose a possible environmental concern.]
- There is a potential risk to other crops from the presence of potentially phytotoxic degradation products in irrigation water. However, the major areas of corn production that use irrigation (Western U.S. corn belt) have deep aquifers with slow recharge rates that are not likely to have sufficient concentrations of the degradation products to adversely affect other crops. In other parts of the U.S., where corn is also grown and where shallow ground water is used for irrigation, sporadic irrigation is used for other crops. Crops such as soybean, which are rotated with corn and are sensitive to irrigation waters containing isoxaflutole residues, could be adversely affected. Estimated maximum concentration of isoxaflutole residues in ground water exceeded the phytotoxic triggers to non-target plants (e.g., other crops) up to 4,500 times, presuming that the degradation products are as toxic as parent isoxaflutole. [Note that updated data since the 1997 assessment indicate that IFT's terminal metabolite, the benzoic acid derivative, does not demonstrate phytotoxicity for terrestrial plants. A developmental toxicity study in rats conducted with the benzoic acid derivative has been submitted to the Agency (MRID 45655906). The results of the study show that in the presence of maternal toxicity at the highest doses tested (750 mg/kg/day), there was no teratogenicity or developmental toxicity. These results and those of other toxicology studies and plant studies on the compounds suggest that the benzoic acid derivative of isoxaflutole is not toxicologically significant.]

On April 16, 2010, EFED completed an ecological risk assessment for an Experimental Use Permit (EUP) request from Bayer for isoxaflutole use on isoxaflutole - resistant soybean. Additionally, EFED conducted another ecological risk assessment expanding the geographic extent of corn and considered the use of isoxaflutole on soybean. In these ecological risk assessments, IFT and its bioactive principle, diketonitrile, were assessed for potential risk to non-target organisms. The conclusions are briefly summarized below:

- The Agency's LOC for terrestrial non-target plants was exceeded for runoff and spray drift exposure routes.
- Runoff from soybean and/or corn fields may contain residues of isoxaflutole and diketonitrile. These waters, if used for irrigation on non-target plants (crops) may exceed the Agency's LOC for non-target plants by up to 310X.
- The Agency's LOC for aquatic non-target plants was not exceeded for listed and non-listed species near soybean fields.

- The Agency's acute or chronic LOCs for birds and mammals (listed and non-listed) were not exceeded.
- The Agency's acute or chronic LOCs for fish or invertebrates (freshwater or estuarine) (listed and non-listed) were not exceeded.

On September 9, 2011, the EPA Health Effects Division (HED) completed a human-health risk assessment entitled *Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment (EPA, 2011b)* as a result of a request from Bayer to amend 40 CFR 180.537 by establishing tolerances for combined residues of isoxaflutole and diketonitrile in or on soybean. Additional information specific to this section may be found in that document. Acute and chronic toxicity profiles are presented below in Tables C3 and C4.

Table C3. Acute toxicity profile of isoxaflutole and degradation products

Guideline No./Study Type	MRID No.	Results	Toxicity Category
Isoxaflutole Technical			
870.1100/Acute oral toxicity	43573212	LD_{50} >5000 mg/kg	IV
870.1200/Acute dermal toxicity	43573213	LD_{50} >2000 mg/kg	III
870.1300/Acute oral toxicity	43573214	LC_{50} >5.23 mg/L	IV
870.2400/Primary eye irritation	43573215	Non-irritating	IV
870.2500/Primary dermal irrigation	43573216	Non-irritating	IV
870.2600/Dermal sensitivity	43573217	Non-sensitizer	N/A
Diketonitrile Technical			
870.1100/Acute oral toxicity	43904810	LD_{50} >5000 mg/kg	IV
Benzoic Acid derivative Technical			
870.1100/Acute oral toxicity	43904812	LD_{50} >5000 mg/kg	IV

Table C4. Subchronic and chronic toxicity and genotoxicity profile: Isoxaflutole and products

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
Isoxaflutole		
870.3250 21-day dermal (rat)	43573219 0, 10, 100, or 1000 mg/kg/day.	NOAEL = 1000 mg/kg/day. LOAEL not observed.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
	Acceptable (guideline)	
870.3700 Developmental toxicity (rat)	43573220 0, 10, 100, or 1000 mg/kg/day. **Acceptable (guideline)**	Maternal NOAEL = 1000 mg/kg/day. Maternal LOAEL = 500 mg/kg/day based on increased incidence of clinical signs and decreased body weight, body-weight gains and food consumption. Developmental NOAEL = 10 mg/kg/day. Developmental LOAEL = 100 mg/kg/day base on decreased fetal body weights and increased incidences of skeletal anomalies.
Developmental toxicity (rabbit)	43904808 0, 5 , 20, 100 mg/kg/day. **Acceptable (guideline)**	Maternal LOAEL = 100 mg/kg/day based on increased incidence of clinical signs, decreased body weight gains, and food consumption. Developmental NOAEL not observed. Developmental LOAEL = 5 mg/kg/day base on increased incidence of fetuses with 27th pre-scaral vertebrae.
870.3800 2-generation reproduction (rat)	43904809 0/0, 0.45/0.46, 1.76/1.79, 17.4/17.7, or 414/437 mg/kg/day (M/F). **Acceptable (guideline)**	Maternal NOAEL = 1.76 mg/kg/day. Maternal LOAEL = 17.4 mg/kg/day based on increased liver weights and hypertrophy in both sexes and generations. Reproductive NOAEL = 437 mg/kg/day. Reproductive LOAEL not observed. Offspring NOAEL = 1.76 mg/kg/day. Offspring LOAEL = 17.4 mg/kg/day based on reduced litter survival in both generations (F_1 and F_2 pups).
870.4100 Chronic toxicity (dogs)	43573218 0, 240, 1200, 12000, or 30000 ppm (0, 8.56/8.41, 44.81/45.33, 453/498, or -/1254 mg/kg/day [M/F]). **Acceptable (guideline)**	Maternal NOAEL = 20 mg/kg/day. Maternal LOAEL = 100 mg/kg/day based on increased incidence of clinical signs, decreased body weight gains, and food consumption. Developmental NOAEL not observed. Developmental LOAEL = 5 mg/kg/day base on increased incidence of fetuses with 27th pre-scaral vertebrae.
870.4200	43904807	NOAEL = 25 ppm (3.24/4 mg/kg/day

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
Carcinogenicity (mice)	0, 25, 500, or 7000 ppm (0/0, 3.2/4, 64.4/77.9, or 977.3/1161.1 mg/kg/day [M/F]). **Acceptable (guideline)**	(M/F). LOAEL = 500 ppm (64.4/77.9 mg/kg/day (M/F), based on decreased body weight gains, increased liver weights, and increased incidences of histopathological liver changes. Liver tumors observed at HDT.
870.4300 Chronic toxicity/ Carcinogenicity (rats)	43904806 0, 0.5, 2, 20, or 500 mg/kg/day. **Acceptable (guideline)**	NOAEL = 2 mg/kg/day. LOAEL = 20 mg/kg/day, based on liver, thyroid, ocular, and nervous system toxicity (M) and liver toxicity (F). Liver and thyroid tumors observed at HDT.
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43588002 Up to insoluable (≥ 500 □g/plate) concentrations =/- S9. **Acceptable (guideline)**	Negative.
870.5300 *In vitro* mammalian gene mutation (L5178Y mouse lymphoma)	43573222 Up to insoluable (≥ 150 □g/plate) or soluable (≤ 75 mg/plate) concentrations +/- S9. **Acceptable (guideline)**	Negative.
870.5375 *In vitro* mammalian chromosomal aberration (lymphocytes)	43573221 Up to insoluable (≥ 300 □g/ml-S9; ≤ 600 □ **Acceptable (guideline)**	Negative.
870.5395 *In vivo* mammalian cytogenetics (mouse micronucleus)	43573223 Up to 5000 mg/kg. **Acceptable (guideline)**	Negative.
870.6200	43904804	NOAEL = 125 mg/kg/day.

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
Acute neurotoxicity (rat)	0, 125, 500, or 2000 mg/kg/day. **Acceptable (guideline)**	LOAEL = 500 mg/kg/day based on significant decreases in hind limb grip strength and landing food splay on day 15.
870.6200 Subchronic neurotoxicity (rat)	43904805 0, 25, 250, or 750 mg/kg/day. **Acceptable (guideline)**	NOAEL = Not observed. LOAEL = 25 mg/kg/day based on significant decreases in mean hind limp grip strength during both trials and week 13 and a non-significant decrease in mean forelimb grip strength at week 13.
870.6300 Developmental Neurotoxicity (rat)	45215701 (2000) 0, 5, 25, or 250 mg/kg bw/day. **Unacceptable (guideline) -** morphometric measurements not performed	Maternal NOAEL = 25 mg/kg/day. Maternal LOAEL = 250 mg/kg/day based on increased incidence of clinical signs, decreased body weight, body-weight gains, and food consumption Tentative offspring NOAEL = 25 mg/kg/day. Tentative offspring LOAEL = 250 mg/kg/day based on decreased body weight and brain weight (no effects at lower doses).
870.7485 Metabolism (rat)	43573224 1 and 100 mg/kg (single dose) 1 mg/kg/day (15-day repeated dosing). **Acceptable (guideline)**	Rapidly and extensively absorbed and metabolized. Diketonitrile represented 70% or more of the radioactivity excreted in the urine and feces. The benzoic acid derivative was more polar. Elimination was rapid and dose dependent. The majority of the radiolabel was eliminated in the first 24 and 48 hours for the low and high dose groups, respectively. The extensive

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
	43904815 Comparative metabolism study **Unacceptable (non-guideline)**	systemic clearance of the radiolabel was reflected in the low levels of radioactivity found in tissues at 168 hours post-dosing. Sex-related differences were observed in the excretion and distribution pattern among high-dose rats. The elimination half-lives were similar among single low and high dose groups, with an estimated mean blood half-life of 60 hours. No sex differences were observed in the metabolism of ^{14}C-isoxaflutole.
870.7600 Dermal penetration	44044702 0.865, 7.32, or 79 mg/cm^2. **Acceptable (guideline)**	3.46% absorption at 0.865 mg/cm^2 after 10 hours.
870.7800 Immunotoxicity	48283101 0, 160, 800, or 4000 ppm (0. 6. 57. or 279 mg/kg/day). **Acceptable (guideline)**	NOAEL = 4000 ppm (279 mg/kg/day). LOAEL = not identified.
Mechanistic studies	43904816-43904820	Investigated ocular toxicity, tyrosinemia, and mode of action of liver and thyroid tumor formation in rats and mice
	Diketonitrile	
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43904811 Up to 500 ± S9. g/plate	Negative.
	Acceptable (guideline)	
	Benzoic Acid derivative	
870.3100 28-day oral rat (range-finding)	43904813 (1995) 0, 150, 500, 5000, or 15000 ppm (0.0, 11,14/12.68, 37.57/42.7, 376.96/421.53 or 1117.79/1268.73 mg/kg/day [M/F]) **Acceptable (guideline)**	NOAEL = 15000 ppm (1117.79/1268.73 mg/kg/day [M/F]). LOAEL not observed.
870.3100	45655903 (1998)	NOAEL = 12000 ppm (769/952 mg/kg/day [M/F]).

Guideline No./Study Type	MRID No. (Year)/Doses/Classification	Results
90-day oral (rat)	0, 1200, 4800, or 12000 ppm (0/0. 73.2/93.1, 306/371, or 769/952 mg/kg/day [M/F]). **Acceptable (guideline)**	LOAEL not observed.
870.3700 Developmental toxicity rats (gavage)	45655906 0, 75, 250, or 750 mg/kg/day. **Acceptable (guideline)**	Maternal NOAEL = 75 mg/kg/day. Maternal LOAEL = 250 mg/kg/day based on clinical signs (salivation and piloerection around time of treatment), decreased body-weight change, decreased corrected body-weight change, and decreased food consumption. Developmental NOAEL = 750 mg/kg/day. Developmental LOAEL not observed.
870.5100 *In vitro* bacterial reverse mutation (*S. typhimurium*)	43904814 Up to cytotoxic concentrations (≥ 2500 □g/plate) - S9. **Acceptable (guideline)**	Negative.
870.5300 *In vitro* mammalian gene mutation (CHO/HGPRT)	4454303 Up to ≥ 2700 □g/ml + - S9. **Acceptable (guideline)**	Negative.
870.5375 *In vitro* mammalian chromosomal aberration (CHO cells)	44545301 Up to ≥ 2710 □g/ml + - S9. **Acceptable (guideline)**	Negative.
870.5395 *In vivo* mammalian cytogenetics (mouse micronucleus)	44545301 0, 500, 1000, or 2000 mg/kg. **Acceptable (guideline)**	Negative.

As a result of this human-health assessment, HED determined that there is no residue chemistry, toxicological or occupational/residential exposure issue that would preclude establishment of an unconditional registration for isoxaflutole and its metabolites. These tolerances include:

- HED-recommended tolerance for the combined residue of isoxaflutole and diketonitrile on soybean is 0.05 ppm.
- HED-recommended tolerance the combined residue of isoxaflutole and diketonitrile on aspirated grain fractions of soybean is calculated as 0.30 ppm.

References

EPA (2011a) "Isoxaflutole Summary Document Registration Review: Initial Docket June 2011." Environmental Protection Agency.

EPA (2011b) "Isoxaflutole. Section 3 Registration for Use on Soybeans. Human-Health Risk Assessment."

EPA (2011c) "Preliminary Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Assessments in Support of the Registration Review of Isoxaflutole." Environmental Protection Agency.

HRAC (2012) "Classification of Herbicides According to Modes of Action." Herbicide Resistance Action Committee. http://www.plantprotection.org/hrac/MOA.html >.

Montague, K. (2012). Personal Communication.

Pallett, KE; Cramp, SM; Little, JP; Veerasekaran, P; Crudace, AJ; and Slater, AE (2001) "Isoxaflutole: the background to its discovery and the basis of its herbicidal properties." *Pest Management Science.* 57 (2): p 133-42. http://dx.doi.org/10.1002/1526-4998(200102)57:2<133::AID-PS276>3.0.CO;2-0 >.

Pallett, KE; Little, JP; Sheekey, M; and Veerasekaran, P (1998) "The Mode of Action of Isoxaflutole: I. Physiological Effects, Metabolism, and Selectivity." *Pesticide Biochemistry and Physiology.* 62 (2): p 113-24. http://www.sciencedirect.com/science/article/pii/S0048357598923781 >.

Ramanarayanan, T; Narasimhan, B; and Srinivasan, R (2005) "Characterization of Fate and Transport of Isoxaflutole, a Soil-Applied Corn Herbicide, in Surface Water Using a Watershed Model." *Journal of Agricultural and Food Chemistry.* 53 (22): p 8848-58. Last Accessed: 2011/11/14 < http://dx.doi.org/10.1021/jf0508596 >.

RSC (2011) "Isoxaflutole." Royal Society of Chemists. http://www.rsc.org/pdf/general/11isoxaf.pdf >.